UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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LINDA ROSI, individually and on behalf of all others similarly situated,

Plaintiff,

-v-

ACLARIS THERAPEUTICS, INC., et al.,

Defendants.

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19-cv-7118 (LJL)

OPINION AND ORDER

LEWIS J. LIMAN, United States District Judge:

Defendants Aclaris Therapeutics, Inc. ("Aclaris" or the "Company"), Neal Walker ("Walker"), Frank Ruffo ("Ruffo"), Kamil Ali-Jackson ("Ali-Jackson"), and Brett Fair ("Fair") (collectively "Defendants"), move, pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6), to dismiss the amended class action complaint filed against them.

For the following reasons, the motion to dismiss is granted in part and denied in part.

BACKGROUND

The Court accepts the well-pleaded allegations of the Amended Complaint and the documents incorporated therein as true for purposes of the motion to dismiss.[1]

[1] In reviewing a Rule 12(b)(6) motion, the court may consider the following materials: "(1) facts alleged in the complaint and documents attached to it or incorporated in it by reference, (2) documents 'integral' to the complaint and relied upon in it, even if not attached or incorporated by reference, (3) documents or information contained in defendant's motion papers if plaintiff has knowledge or possession of the material and relied on it in framing the complaint, (4) public disclosure documents required by law to be, and that have been, filed with the Securities and Exchange Commission, and (5) facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence." *In re Merrill Lynch & Co. Research Reports Sec. Litig.*, 568 F. Supp. 2d 349, 352 n.1 (S.D.N.Y. 2008). With one exception, Plaintiff does not object to the exhibits submitted by Defendants, which are incorporated in or otherwise integral to the Amended Complaint.

A. The Parties

Plaintiff Robert Fulcher ("Plaintiff" or "Fulcher") brings a putative class action on behalf of persons and entities that purchased or otherwise acquired Aclaris securities between May 8, 2018 and August 12, 2019, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' alleged violations of the federal securities laws under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder.

Aclaris is a small physician-led biopharmaceutical company headquartered in Wayne, Pennsylvania. Dkt. No. 27 ("Amended Complaint" or "AC") ¶ 2. Until August 2019, its business was focused on the identification, development, and commercialization of therapies to address unmet needs in medical and aesthetic dermatology and immunology. *Id.* ¶¶ 2, 52.[2] Its shares trade on the NASDAQ Global Select Market under the symbol "ACRS." *Id.* ¶¶ 36, 53. The "Individual Defendants" are defined to include Walker who was President and Chief Executive Officer ("CEO"), *id.* ¶ 37, Ruffo who was Chief Financial Officer ("CFO"), *id.* ¶ 38, Ali-Jackson who was Chief Legal Officer, Chief Compliance Officer and Corporate Secretary, *id.* ¶ 39, and Fair who was Chief Commercial Officer, *id.* ¶ 40. Walker, Ruffo, and Ali-Jackson had worked together at prior pharmaceutical start-up companies and were the co-founders of Aclaris. *Id.* ¶ 54. They, along with Aclaris's Chief Operating Officer, Chis Powala ("Powala"), ran Aclaris and acted as the core management of the Company. *Id.* ¶ 54.[3]

[2] After August 2019, Aclaris ceased its focus on medical and aesthetic dermatology needs. AC ¶ 52.

[3] The Individual Defendants other than Fair are alleged to have been employed in their positions "at all relevant times." Fair is alleged to have been Chief Commercial Officer throughout the Class Period until February 8, 2019, when he was no longer employed by the Company. AC ¶ 40. Powala is not a defendant in this action.

Aclaris was incorporated in 2012 and went public in October 2015. *Id.* ¶ 53. Because Aclaris did not sell products at that time, Defendants funded Aclaris's operations with the proceeds of the initial public offering. *Id.* ¶ 57. At the start of the Class Period in May 2019, Aclaris was in dire financial condition. *Id.* ¶ 56. It had never produced revenue from product sales and was experiencing increasing operating losses, which had ballooned from $8.5 million in 2014 to $72.4 million in 2017 and to $30.9 million in the first quarter of 2018 alone. *Id.* It also had few employees. *Id.* ¶ 55. It had 96 full-time and part-time employees as of December 31, 2017, and 169 full-time and part-time employees as of December 31, 2018. *Id.* In August 2019, it laid off approximately 86 employees, or half of Aclaris's staff. *Id.*

B. ESKATA

On December 14, 2017, five months before the start of the Class Period, the FDA approved ESKATA ("ESKATA" or "Eskata"), which was a concentrated (40%) hydrogen peroxide-based topical solution for treatment of raised seborrheic keratosis ("SK" or "raised SK"), or waxy or wart-liked raised brown spots or lesions on the skin that are darker than an individual's regular skin tone. *Id.* ¶¶ 4, 58, 62. They are colloquially known as "age spots." *Id.* ¶ 58. SK lesions are typically treated by dermatologists who usually remove them by freezing them off (cryosurgery), by cutting (shave excision), by scraping and burning (electrodessication and curettage) or a combination of those methods. *Id.* ¶ 60. Those treatments are painful, leave scars, and cause skin discoloration and some patients thus avoid them, preferring to live with the SKs. *Id.* ¶ 61. Approximately 83 million Americans have raised SK. *Id.* ¶ 59.

Aclaris developed ESKATA as an alternative clinical treatment to removing SK lesions without damaging surrounding skin. *Id.* ¶ 63. ESKATA offered advantages to existing raised SK treatments that were invasive and painful and could leave scars or skin discoloration. *Id.* ¶¶ 5, 66. ESKATA was administered through an applicator, which looked like a thin felt-tipped

pen or highlighter, by a healthcare provider. *Id.* ¶ 63. The healthcare provider would rub the tip of the applicator directly to the lesion for approximately 20 seconds to coat the lesion with ESKATA, four times, approximately one minute apart. If the application was successful, the raised SK treated with ESKATA would peel away in the days following treatment. If the lesion was not removed by a single treatment, a patient would return for additional treatments. *Id.*

ESKATA was Aclaris's only FDA-approved product and therefore far and away the Company's most important product. *Id.* ¶¶ 4, 62. Aclaris's ability to continue as a going concern depended on whether it could successfully market ESKATA. *Id.* ¶ 62.

1. FDA Approval

When the FDA approved ESKATA, the label for ESKATA was published on the FDA website. *Id.* ¶ 64; Dkt. No. 37 ("Vigna Decl."), Ex B. The FDA warning label reflected that ESKATA could cause undesirable side effects. Those side effects included "eye disorders" and "local skin reactions," which were listed in three different locations on the label: in two separate areas labelled "warnings and precautions" and under "patient counseling information." Vigna Decl., Ex. B. Possible eye disorders included corneal injury (erosion, ulceration, perforation, and scarring), chemical conjunctivitis, eyelid edema, severe eye pain, or permanent eye injury, including blindness." *Id.*

Skin reactions were also observed "in and around the treatment area after application of ESKATA." *Id.* "Common local skin reactions" observed included, 10 minutes after treatment, erythema, stinging, edema, pruritus, and vesiculation; 1 week after treatment, scaling, erythema, crusting, pruritus, erosion, and ulceration; and 15 weeks after treatment, erythema, hyperpigmentation, scaling, crusting, and hypopigmentation. *Id.* The label also warned that "severe reactions, including ulcerations and scarring, may occur." *Id.* "Severe local skin reactions included erosion, ulceration, vesiculation and scarring." *Id.*; *see also id.* ("Severe skin

reactions can include: breakdown of the outer layer of the skin (erosion), ulcers, blisters and scaring."). "The most common side effects of ESKATA include: itching, stinging, crusting, swelling, redness and scaling." *Id.*

Aclaris published the warning label on its websites and announced it in a Form 8-K filed on December 15, 2017 with the U.S. Securities and Exchange Commission ("SEC"). *See* Vigna Decl., Ex. O.

2. Marketing Plan

Aclaris began marketing ESKATA in 2018 through a two-phase marketing plan. AC ¶¶ 7, 71. The first phase, called the "ESKATA Early Experience Initiative," was launched in spring 2018 ("EEI"). It involved Aclaris's sales representatives visiting physicians to encourage them to order ESKATA. *Id.* ¶¶ 7, 9, 71. Aclaris hired approximately 50 sales representatives to introduce ESKATA to hundreds of dermatologists. *Id.* ¶¶ 73-75. The sales representatives offered free samples of ESKATA, sat in on treatments of patients using ESKATA, and after the treatments, surveyed the physicians and patients on, among other things, a patient's pain or comfort level and how effectively ESKATA removed raised SK. *Id.* ¶¶ 7, 71, 73.

After the EEI was underway, on March 29, 2018, the FDA's Office of Prescription Drug Promotion ("OPDP") sent Defendants a letter (the "March 2018 Letter"), recommending that Aclaris "revise proposed presentations [for ESKATA] so that they do not omit material information regarding the risks associated with ESKATA or otherwise misrepresent important risk information" and also recommending that "Aclaris revise proposed presentations so that they did not overstate the efficacy of ESKATA." *Id.* ¶ 123.[4] ESKATA became commercially available on May 7, 2018. *Id.* ¶ 90.

[4] The March 2018 Letter is not attached to the Amended Complaint and was not submitted by either party.

The second phase of the marketing plan was a direct-to-consumer marketing campaign (the "DTC campaign") designed to drive patients to physicians to request ESKATA treatments. The DTC campaign kicked off on or about September 19, 2018, with an interview of dermatologist Doris Day, a paid Aclaris spokesperson, that aired on the popular daytime talk show, "The View." *Id.* ¶¶ 8, 106, 108. During the interview, Dr. Day discussed ESKATA's application and treatment potential, as well as certain side effects. Dr. Day said, "[T]ypically in one or two treatments the lesions go away, they resolve, and that's the end of it." *Id.* ¶ 109. Dr. Day also warned that ESKATA "can sting as you apply it." *Id.* ¶ 111.

Two sets of "before and after" photos were displayed showing certain patients' results. The first set of images presented a patient with over 10 raised SK before treatment and showed that all of the lesions were completely removed after treatment and without skin discoloration. The second set of images presented a patient with fewer raised SK but also indicated that all of the raised SK were completely removed after treatment and without skin discoloration. *Id.* ¶ 110. Dr. Day stated: "[S]o you can see from the before and after what it [treatment with ESKATA] looks like." *Id.* ¶ 111. The photographs were accompanied by on-screen disclaimers stating: "18% of patients experienced clearance of 3 out of 4 raised SKs treated with ESKATA vs. 0% with vehicle (Day 106 of study)"; "[m]ost common side effects are itching, stinging, crusting, swelling, redness and scaling"; and "[a]ctual patient. Individual results may vary." *Id.* ¶ 111. Dr. Day concluded: "I am one of many I think that have their own insecurities about the spots as we age, we get older, good to know though it is not dangerous and there is a way to get rid of them." *Id.* ¶ 112.

According to a confidential witness (CW7), who was Aclaris's executive director of medical affairs between April 2018 and September 2019, Aclaris's director of medical

information told him that the script for "The View" segment was drafted and revised at "highly contentious" Promotions, Regulatory, and Compliance ("PRC") meetings attended by Defendant Ali-Jackson, and Ali-Jackson was editing the segment's script "up to the last minute." *Id.* ¶¶ 49, 115.[5] In addition, Ali-Jackson and other members of Aclaris's senior leadership team were on site when the segment was taped. *Id.* CW7 stated that he also learned from the then-director of medical information at Aclaris that the script was escalated to Defendants Walker, Ruffo, Ali-Jackson, Fair, and other senior leadership after it was debated in PRC meetings. *Id.* ¶ 115.

Shortly after the segment aired, Defendants made a recording of it available on Aclaris's Facebook and LinkedIn pages. *Id.* ¶¶ 8, 116. The video was also posted to the website YouTube.com as well as on a channel devoted to episodes of "The View." *Id.* ¶ 116. Defendants also loaded the segment on iPads that sales representatives brought to meetings with physicians and patients. *Id.*

Over time, the second phase involved releasing print advertising as well as a television commercial promoting ESKATA as a low-risk and effective way to remove raised SK. *Id.* ¶¶ 8, 72. For example, a 60-second television commercial for ESKATA included both sets of before-and-after photographs that appeared on "The View" and a promotional brochure for ESKATA that physicians could distribute to patients included before-and-after showing that ESKATA completely removed SKs. *Id.* ¶ 118. "Stand-up banners" promoting SK and given by ESKATA sales representatives to physicians used one of the sets of before-and-after photographs from "The View" without the disclaimer that "18% of patients experienced clearance of 3 out of 4 raised SKs treated with ESKATA vs. 0% with vehicle (Day 106 of study)"; one of those

[5] The Amended Complaint refers to all confidential witnesses "in the masculine to protect their identities." AC ¶ 42.

images presented a patient with over ten raised SKs that purported to show that all ten of the lesions were completely removed without scarring. *Id.* ¶ 119. Print advertisements also used the images from "The View," including of the patient who had ten SKs removed. *Id.* ¶ 120.

3. Patient Experiences

Three of Aclaris's 50 sales representatives (CW3, CW4, and CW9), a sales manager (CW8), and an account specialist (CW5), who are listed as confidential witnesses, reported learning that patients experienced pain while receiving ESKATA treatments. *Id.* ¶¶ 45-47, 50-51, 76. Those reports were consistent with some patient reviews posted over time on the internet. *Id.* ¶ 84; *see id.* ¶¶ 87-94.

One of the sales representatives (CW3) reported that after hearing from physicians and patients about pain in ESKATA treatments, he began providing pain training to physicians even though Defendants' materials and training did not provide such training. *Id.* ¶¶ 45, 76.[6] He had personally witnessed at least one patient refuse to continue ESKATA treatments because it was too painful. *Id.* ¶ 76. Another sales representative (CW4) said that customers told him that ESKATA "hurt people," left scars, and resulted in hyperpigmentation, and he offered that ESKATA "behaved very differently than the way [Defendants] presented it" and "[f]rom the way it actually behaved in the field, I never would have taken it to market." *Id.* ¶ 77. The third sales representative (CW9) said that physicians and patients he worked with had extremely negative experiences with ESKATA, including adverse side effects and limited effectiveness; he said that he received complaints about adverse side effects and that the product required many applications to get results. *Id.* ¶ 81.

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[6] The account specialist (CW5) and a sales representative (CW9) confirmed the unremarkable fact that the first time they saw how ESKATA operated in practice was during the EEI. AC ¶ 75.

The sales manager (CW8) said that multiple customers reported that ESKATA caused burning and stinging, left large white spots on treated areas, and was not as effective as it had been described; these complaints were reported through Aclaris's system for reporting adverse side effects. *Id.* ¶ 79. CW8 was of the view that ESKATA had the same side effects as existing methods of removing SKs but was more expensive. *Id.* ¶ 80. CW5, the account specialist, stated that ESKATA's adverse effects were "more severe than anyone was prepared for," and included on-site reactions, swelling, and bubbling as if the skin were burning, that he discussed these problems with his peer sales representatives, and that the problems were escalated to "senior leadership" at Aclaris, which was "completely defensive" and that these complaints were "blown off." *Id.* ¶ 78. CW9, one of the sales representatives, said that, as a member of the executive sales team charged with improving sales, he attended meetings at Aclaris's headquarters between August and October 2018, which were also attended by Walker and Fair. *Id.* ¶ 98. At those meetings, members of the executive sales team discussed the complaints sales representatives had received from physicians and patients about adverse side effects and efficacy, including that the drug took many more applications to achieve results than the physicians had been told when they were sold the product. *Id.*

Patients also provided reviews of ESKATA on the internet. *See id.* ¶¶ 87-94 (reviews in May 2018, September 2018, January 2019, June 2019, and September 2019). For example, on May 7, 2018—the same day that ESKATA became commercially available—a patient wrote on the ESKATA review page on Drugs.com that "[a]fter one treatment none of my SK was gone. Seeing the doctor tomorrow and expect that she will recommend another treatment on same spots for another $200. Very disappointed." *Id.* ¶ 90. In September 2018, one patient posted on the ESKATA review page on WebMD.com that that the patient had had three treatments with

ESKATA for SKs and that with a thin SK "it usually comes off in one treatment, but with thicker ones, it seems just to burn off the top layer." *Id.* ¶ 87. The patient wrote that he was going back for a fourth treatment on the same SKs, which were partially but not completely gone, and that the medication burned for about 30 minutes when applied and then turned the affected area white for a couple of hours. *Id.* Also in September 2018, another patient wrote on the ESKATA review page on Drugs.com site: "Had treatment on face. Burned a lot all over, could not open my eyes for about 30 minutes, worst experience of my life. I don't recommend this product to anyone." *Id.* ¶ 91. A January 2019 reviewer noted that ESKATA "burns like hell" and "made my face look like someone through [sic] hot oil on it" and that none of the patient's SKs had disappeared. *Id.* ¶ 92.[7]

Behind the scenes at Aclaris and during the DTC campaign, CW7, who reported to Aclaris's chief medical officer (who in turn reported to the CEO), repeatedly raised concerns at the twice-weekly PRC meetings that the marketing materials and other publications promoting ESKATA were misrepresenting the product's safety and effectiveness. *Id.* ¶ 125. Each PRC meetings was attended by Ali-Jackson. *Id.* According to CW7, the concerns were documented and the legal team and Ali-Jackson settled the disputes that were not escalated to Walker, Ruffo, and Fair. *Id.* ¶ 125. In particular, CW7 expressed concerns at PRC meetings attended by Ali-Jackson that the marketing materials Aclaris was planning to use were not consistent with the guidance that the Company had received in the March 2018 Letter. *Id.* ¶ 127. In response to his concerns, CW7 was told that Aclaris had decided to take a bigger risk and the individual Defendants "want to look at (the data) this way," and not make changes to the marketing

[7] Plaintiff also cites to an article from the American Family Physician, but that article is dated November 2019 and after the Class Period. AC ¶ 83 & n.2.

materials. *Id.* CW7 was told by the then-medical director, who reported to CEO Walker, that CW7 should stop raising concerns because "dermatology pharmaceutical companies do things differently." *Id.* CW7 also attended many meetings with Ali-Jackson, Walker, Ruffo, and Fair that occurred because concerns about misleading claims about ESKATA's effectiveness and risks had been raised during PRC meetings. *Id.* ¶ 126.

C. The June 2019 FDA Letter

On June 20, 2019, the FDA publicly disclosed that the OPDP had sent Defendants an untitled letter dated June 14, 2019 (the "June 2019 Letter"), finding that the segment on "The View" contained "false or misleading claims and/or representations about the risks associated with and the efficacy of [ESKATA]" in violation of the Federal Food, Drug and Cosmetic Act ("FFDCA"). Vigna Decl., Ex. N; *see* AC ¶¶ 22, 157-61. The June 2019 Letter referenced the OPDP's March 2018 Letter, stating:[8]

> OPDP notes that our advisory comments dated March 29, 2018, addressed draft Aclaris presentations for Eskata with certain similarities to the video in this letter. In these advisory comments, OPDP recommended that Aclaris revise proposed presentations so that they did not omit material information regarding the risks associated with Eskata or otherwise misrepresent important risk information. We also recommended that Aclaris revise proposed presentations so that they did not overstate the efficacy of Eskata. We are concerned that Aclaris is promoting Eskata in a manner that fails to adequately present the serious risks of the drug or describe

[8] As alleged, "[u]ntitled letters identify violations of federal law caused by a company's omission of risk information, minimization of risk information, broadening or inadequate communication of indication, overstatement of efficacy or unsubstantiated claims. According to the FDA, untitled letters, among other things, request immediate correction of any regulatory violations that may not meet the threshold of regulatory significance for a 'warning letter.' Although an untitled letter does not state that failure to promptly correct a violation may result in an enforcement action against the violator, the FDA is not obligated to warn individuals or firms about violations before taking enforcement action. Accordingly, an enforcement action can follow an untitled letter if the violations described in the untitled letter are not resolved." AC ¶ 158.

> the efficacy of the drug in a truthful and non-misleading manner despite this direction from OPDP.

Vigna Decl., Ex. N at 2.

With regard to claims about serious risks, the June 2019 Letter first stated the video failed "to reveal the serious risks that are reflected in the warnings and precautions for the drug and are intended to be communicated to patients as described in the PI and Patient Information (PPI)." *Id*. Specifically, the video failed "to include information regarding the serious risks associated with [ESKATA], which bears warnings and precautions related to the risks of serious eye disorders (such as permanent eye injury including blindness) in the case of exposure to the eye and severe skin reactions including scarring." *Id.* at 1. Although the FDA "acknowledge[d] that in addition to the Physician Spokesperson referring consumers to Eskata.com for more information, the video includes superimposed text (SUPERs) listing the drug's most common side effects and directing consumers to Eskata.com for full safety and prescribing information," it stated that these references did "not mitigate the video's omission of the serious risk information regarding the warnings and precautions about serious eye disorders that can result from unintended exposure and about severe local skin reactions." *Id.* "By omitting the warnings and precautions associated with Eskata, the video fails to provide material information about the consequences that may result from the use of the drug and creates a misleading impression about the drug's safety." *Id.*

With regard to claims about common adverse reactions, the June 2019 Letter also stated that "it is misleading for the Physician Spokesperson to state that patients can experience stinging upon application, without disclosing the other most common local adverse reactions, many of which occur within minutes of treatment with Eskata." *Id.* at 3. The video failed to disclose other "common local adverse reactions" of erythema, edema, scaling, crusting, and

pruritus, and failed to disclose that many of these reactions occurred immediately after treatment. *Id.* It was also misleading for the ESKATA spokesperson to suggest that "one or two treatments" is typically "the end of it" because local adverse reactions have been observed up to 15 weeks after treatment with ESKATA. *Id.* And although the common side effects are listed as SUPERs, the first of the SUPERs contained efficacy information unrelated to the product's risks, and further, the SUPERs were presented with "attention-grabbing photographs" of patients' before-and-after treatments and the spokesperson statement at a "fast pace over approximately 10 seconds" and which "all competes for the consumer's attention." *Id.* The June 2019 Letter stated that, "[a]s a result, it is difficult to adequately process and comprehend the common side effects disclosed in the SUPERs." *Id.* at 3-4.

With respect to claims about efficacy, the June 2019 Letter expressed the concern that by displaying photographs showing the complete clearance of all treated SK lesions, the video created a misleading impression that the typical patient treated with ESKATA would experience similar results whereas, in fact, "only 4% and 8% of subjects treated with Eskata achieved clearance of 4 out of 4 SK lesions at Day 106" in clinical studies. *Id.* at 4-5.

The June 2019 Letter requested Aclaris immediately cease the violations set forth in the letter or, in the alternative, if Aclaris believed it was in compliance with law, to respond to the FDA with its "reasoning and any supporting information for our consideration." *Id.* at 5.

In the wake of this disclosure, the share price of Aclaris common stock fell $0.57 per share, or over 11%, over two consecutive trading sessions to close at $4.54 per share on June 21, 2019, on unusually heavy trading volume. AC ¶¶ 24, 163.

At some time following the June 2019 Letter, and rather than revising the marketing materials, Defendants decided to simply stop marketing ESKATA. *Id.* ¶ 167. In addition, the

videos of the segment on "The View" were pulled from the sales representatives' iPads and sales representatives were instructed to destroy all ESKATA marketing materials, as well as to go to the offices of physicians who had large stand-up banners promoting ESKATA and ask those officers to remove the banners. *Id.* ¶ 166.

D. Aclaris Abandons Commercialization of ESKATA

On August 8, 2019, Defendants issued a press release announcing Aclaris's financial results for the second quarter of 2019. *Id.* ¶ 168. In that press release, Aclaris disclosed that it was discontinuing the commercialization of the ESKATA in the United States "due to the fact that revenues from product sales were insufficient for Aclaris to sustain continued commercialization as a result of the product not achieving sufficient market acceptance by physicians and patients." *Id.* ¶¶ 22, 27, 168. In the wake of this announcement, Aclaris's share price fell $0.15 per share, or over 14%, over two consecutive trading sessions to close at $0.84 per share on August 12, 2019, on unusually heavy trading volume. *Id.* ¶¶ 28, 169. This action followed.

PROCEDURAL HISTORY

The complaint in this action was filed by Linda Rosi on July 30, 2019 and assigned to Judge Laura Taylor Swain. Dkt. No. 1. It was referred to Magistrate Judge James L. Cott for general pretrial purposes. Dkt. No. 5. On November 6, 2019, Judge Cott issued an opinion and order granting a motion to consolidate this case with a similar action filed by Fulcher on September 5, 2019, appointing Fulcher as lead plaintiff, and approving the appointment of Pomerantz LLP as lead counsel. Dkt. No. 17; *see Fulcher v. Aclaris Therapeutics, Inc.*, No. 19-cv-8284 (S.D.N.Y.).[9]

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[9] The Court had directed the Clerk of Court to change the caption of the action to reflect Fulcher as lead plaintiff, Dkt. No. 17, but the caption of this case remains *Rosi v. Aclaris Therapeutics,*

Plaintiff filed the amended complaint on January 24, 2020. Dkt. No. 27. Defendants moved to dismiss the amended complaint on April 17, 2020. Dkt. No. 36. The opposition and reply briefs were submitted on June 15, 2020, Dkt. No. 45, and August 4, 2020, Dkt. No. 46, respectively. That briefing also contained a request by Plaintiff to strike an article submitted by Defendants in connection with their opposition brief. Dkt. No. 44.

The Court held oral argument on February 25, 2021. Dkt. No. 49.

LEGAL STANDARD

A. Motion to Dismiss

"On a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the court must accept as true all factual allegations in the complaint and draw all possible inferences from those allegations in favor of the plaintiff." *Chapman v. Mueller Water Prod., Inc.*, 466 F. Supp. 3d 382, 395 (S.D.N.Y. 2020). This requirement "is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

A complaint must offer more than "labels and conclusions," or "a formulaic recitation of the elements of a cause of action" or "naked assertion[s]" devoid of "further factual enhancement" in order to survive dismissal. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 557 (2007). The ultimate question is whether "[a] claim has facial plausibility, [i.e.,] the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. Put another way, the

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plausibility requirement "calls for enough fact to raise a reasonable expectation that discovery will reveal evidence [supporting the claim]." *Twombly*, 550 U.S. at 556; *see also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 46 (2011) (same). "[A]t the motion to dismiss stage, courts 'may consider any written instrument attached to the complaint, statements or documents incorporated by reference, legally required public disclosure documents . . . and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit.'" *In re Synchrony Fin. Sec. Litig.*, 988 F.3d 157, 171 (2d Cir. 2021) (quoting *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd*., 493 F.3d 87, 98 (2d Cir. 2007)). A plaintiff "may not cherry pick certain public statements for its complaint and divorce them from the universe of disclosed information to plausibly allege fraud." *Id.*

B. Section 10(b) and Rule 10b-5

"Securities fraud cases are often complex and costly, so the pleading standards for such cases are demanding." *In re Synchrony*, 988 F.3d at 161. To plead a claim for damages under Section 10(b) and Rule 10b 5, a plaintiff must satisfy each of the following six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation; (5) economic loss; and (6) loss causation." *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 267 (2014); *accord Matrixx*, 563 U.S. at 37-38; *Waggoner v. Barclays PLC*, 875 F.3d 79, 93 n.23 (2d Cir. 2017).

To be actionable, a misrepresentation or omission must be material, i.e., a plaintiff must allege facts showing that there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Ganino v. Citizen Utils. Co.*, 228 F.3d 154, 162 (2d Cir. 2000) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231 32 (1988)). "In judging whether an alleged

omission was material in light of the information already disclosed to investors, [the court] consider[s] whether there is 'a substantial likelihood that the disclosure of the [omitted material] would have been viewed by the reasonable investor as having significantly altered the total mix of information [already] made available.'" *In re ProShares Tr. Sec. Litig.*, 728 F.3d 96, 102 (2d Cir. 2013) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). However, Section 10(b) and Rule 10b 5(b) "do not create an affirmative duty to disclose any and all material information." *Matrixx*, 563 U.S. at 44. "Materiality alone does not demand disclosure, nor does the duty to disclose encompass non-material information." *In re ProShares*, 728 F.3d at 102 (quoting *Panther Partners, Inc. v. Ikanos Comm'ns, Inc.*, 538 F. Supp. 2d 662, 668 (S.D.N.Y. 2008)).

"'The test for whether a statement or omission is materially misleading' . . . is not whether the statement is misleading in and of itself, but 'whether the defendants' representations, taken together and in context, would have misled a reasonable investor.'" *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 250 (2d Cir. 2016) (quoting *Rombach v. Chang*, 355 F.3d 164, 172 n.7 (2d Cir. 2004)). This test is objective and looks to the understanding of the "ordinary investor." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 187 (2015). Moreover, under the federal securities laws, "literal accuracy is not enough. An issuer must as well desist from misleading investors by saying one thing and holding back another." *Id.* at 192. Companies have a duty of disclosure "only when necessary 'to make . . . statements made, in light of the circumstances under which they were made, not misleading.'" *Matrixx*, 563 U.S. at 44 (citation omitted). "Even when there is no existing independent duty to disclose information, once a company speaks on an issue or topic, there is a duty to tell the whole truth." *Meyer v. Jinkosolar Holdings Co., Ltd.*, 761 F.3d 245, 250 (2d Cir. 2014).

The Private Securities Litigation Reform Act of 1995 ("PSLRA") and Rule 9(b) of the Federal Rules of Civil Procedure impose additional requirements on a plaintiff bringing a private securities fraud action. *See* 15 U.S.C. § 78u-4(b)(1). The "complaint [must] specify each statement alleged to have been misleading, the reasons or reason why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint [must] state with particularity all facts on which that belief is formed." *Id.* "[A] plaintiff must: (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *In re Synchrony*, 988 F.3d at 167 (quoting *Anshutz Corp. v. Merrill Lynch & Co., Inc.*, 690 F.3d 98, 108 (2d Cir. 2012)). A plaintiff cannot plead "the materiality of the alleged misstatements or omissions . . . in a conclusory or general fashion." *In re JP Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595, 626 (S.D.N.Y. 2005); *see In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 367 (E.D.N.Y. 2013) ("The materiality of allegedly false financials may not be pled in a conclusory or general fashion."). "[P]laintiffs 'must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so.'" *Okla. Firefighters Pension & Ret. Sys. v. Xerox Corp.*, 300 F. Supp. 3d 551, 564 (S.D.N.Y. 2018), *aff'd sub nom. Ark. Pub. Emps. Ret. Sys. v. Xerox Corp.*, 771 F. App'x 51 (2d Cir. 2019) (citation omitted).

Moreover, under the PSLRA, where the complaint alleges securities fraud, the plaintiff must allege scienter by "stat[ing] with particularity facts giving rise to a strong inference that the defendant acted with the requisite state of mind." 15 U.S.C. § 78u-4(b)(2). Under this heightened pleading standard for scienter, a plaintiff will sufficiently allege scienter and a complaint will survive, "only if a reasonable person would deem the inference of scienter cogent

and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). In determining whether a strong inference exists, the allegations are not to be reviewed independently or in isolation, but the facts alleged must be "taken collectively" and "the court must take into account plausible opposing inferences." *Id.* at 323.

To establish scienter, a plaintiff must allege specific facts "(1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI*, 493 F.3d at 99; *see ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. J.P. Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009) (same). A plaintiff is required to allege scienter "with respect to each act or omission." 15 U.S.C. § 78u-4(b)(2)(A). While the Court must assess all of the scienter allegations collectively, "[s]everal insufficient allegations of recklessness can never add up to a compelling inference of scienter." *Thomas v. Shiloh Indus., Inc.*, 2017 WL 1102664, at *6 (S.D.N.Y. Mar. 23, 2017).

DISCUSSION

A. False or Misleading Statements

Plaintiff alleges that Defendants violated the federal securities laws in their quarterly earnings calls when they:

- Falsely and misleadingly "told investors that patients 'enjoyed' ESKATA, found it 'comfortable,' and that the treatment 'works' and 'resolves well'" on the earnings calls for the first and second quarters of 2018, AC ¶ 129; *see id.* ¶¶ 130-133; and disclosed "the results of 'surveys' that misleadingly suggested that ESKATA was effective and tolerated well by patients, when in fact physicians and patients found the treatment painful and/or limited in effectiveness" on the earnings calls for the first and second quarters of 2018, *id.* ¶ 129; *see id.* ¶¶ 134-37;

- Falsely "attributed ESKATA's poor sales to the fact that patients needed fewer treatments than expected to remove their raised SK" on the earnings call for the third quarter of 2018. *Id.* ¶ 129; *see id.* ¶¶ 138-40;

- Falsely and misleadingly "touted the Company's DTC advertising campaign while failing to disclose that the campaign was designed to mislead patients as to the risks and effectiveness of ESKATA in violation of the FFDCA" on the earnings calls for the second and third quarters of 2018. *Id.* ¶ 129; *see id.* ¶¶ 141-45.

These quarterly earnings calls were attended by Walker, Ruffo, Ali-Jackson, Chief Scientific Officer Stuart D. Shanler and, until he ceased being an officer of the company in February 2019, by Fair.

Plaintiff also claims Defendants violated the federal securities laws in their SEC filings when:

- Aclaris failed to disclose "the risk of regulatory action created by Defendants' violations of the FFDCA" in the 10-K for 2017, the 10-Qs for the second and third quarters of 2018, the 10-K for 2018, and the 10-Qs for the first and second quarters of 2019. *Id.* ¶ 129; *see id.* ¶¶ 146-51;

- Walker and Ruffo signed the Sarbanes-Oxley Act ("SOX") certifications, attesting that the SEC filings were not materially misleading. *Id.* ¶¶ 152-56.

The statements upon which Plaintiff bases this action are discussed further below.

1. Statements about Patients' Reactions and the ESKATA Early Experience Initiative

Plaintiff challenges the following statements made regarding patient's reactions by Defendant Fair during Aclaris's first quarter and second quarter earnings calls on May 8, 2018, and August 3, 2018, respectively:

- During the first quarter earnings call, when asked how the efficacy of ESKATA in the "limited sort of trial right now compared to what [Aclaris] saw in the clinical trial setting," Fair's response that "[t]he patients enjoy it, it seems to be a comfortable treatment, we're getting a lot of positive feedback on that." *Id.* ¶ 131;

- During the second quarter earnings call, Fair's opening remarks: "[W]e are seeing favorable patient outcomes with the product." *Id.* ¶ 132;

- In the same call, Fair's response to an analyst question about anecdotes from the EEI, surprises, and the willingness of physicians to embrace the product: "[T]he product really works, and I'm pleased. I mean, that sets us up really well for the long term. But, this product really works . . . It's a comfortable treatment. It's easy. It's quick. And the patients look good the next day. It resolves well, you don't have a lot of the

edema and crusting and bleeding that you do with some of the other procedures they're currently using." *Id.* ¶ 132; *see* Vigna Decl., Ex. J. at 17.

Plaintiff also challenges the following statements made regarding the EEI surveys on the same calls:

- During the first quarter earnings call, Fair's opening remarks: "[W]e conducted both physician and patient surveys, which enabled us to understand how ESKATA delivers on its value proposition. Here's some of the takeaways from those surveys: 80% of physicians indicated that applying ESKATA is easy or extremely easy. Physicians indicated it only takes 10 minutes on average to apply ESKATA. And 67% of physicians indicated that they would be comfortable delegating the application of ESKATA to another trained HCP in the office" and "The patient feedback is also very encouraging. Over 96% of patients said that the ESKATA treatment application was easy and completed in a reasonable amount of time. 81% of patients indicated that the day after treatment, they were comfortable enough in their appearance to go out socially. And 86% said that they would recommend the ESKATA treatment to their friends." AC ¶ 135; Vigna Decl., Ex. I;

- During the second quarter earnings call, Fair's statement that "ESKATA provides an excellent treatment option for patients with raised SK." AC ¶ 136;

- In the same call, Fair's statement: "Over 80% of physicians indicated that applying ESKATA is easy or extremely easy. 67% of physicians indicated that they would be comfortable delegating the application of ESKATA to another trained HCP in the office. An additional 15% will determine delegation once they've had more hands-on experience with the product. Over 90% of patients said that ESKATA treatment application was easy and was completed in a reasonable amount of time. Over 80% of patients indicated that the day after treatment they were comfortable enough with their appearance to go out socially. 85% of patients said that they would recommend ESKATA treatment to their friends and, if previously treated, over 90% of patients said that they would recommend ESKATA over prior treatment methods." *Id.*; *see* Vigna Decl., Ex. J at 6.

Plaintiff alleges that these statements were false and misleading because they were inconsistent with the reports from the Aclaris sales representatives, account manager, and sales manager that patients found that ESKATA was painful, did not completely remove lesions, and left persistent skin discolorations. AC ¶¶ 133, 137. He also claims that these statements concealed the risk that ESKATA could not be successfully commercialized since it was limited

in effectiveness, painful, left skin discoloration and thus was no better than existing alternatives. *Id.*

Portions of these statements constitute corporate puffery or opinion. The Second Circuit has held that "words like 'encouraging' are the type of 'expressions of puffery and corporate optimism' that do not generally 'give rise of securities violations.'" *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 153 (2d Cir. 2013) (quoting *Rombach*, 355 F.3d at 174). They either are insufficiently concrete to induce reliance by a reasonable investor (i.e., puffery), or they are non-actionable statements of opinion. Opinions are actionable only if accompanied by allegations that "(1) 'the speaker did not hold the belief she professed,' (2) 'the supporting fact[s] [Defendants] supplied were untrue,' or (3) the stated opinion, 'though sincerely held and otherwise true as a matter of fact,' 'omit[ted] information whose omission ma[de] the [stated opinion] misleading to a reasonable investor.'" *Chapman*, 466 F. Supp. 3d at 398 (quoting *Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016); *Omnicare*, 575 U.S. at 186); *see also Liu v. Intercept Pharms., Inc.*, 2020 WL 1489831, at *5 (S.D.N.Y. Mar. 26, 2020).

Fair's statement in the first quarter of 2018 that patient feedback was "very encouraging," and his statement, in the second quarter, regarding his view that the patient outcomes Aclaris was seeing were "favorable," the fact that he was "pleased" with ESKATA's performance, and his characterization of ESKATA as providing an "excellent treatment option," all fall into these categories. The Amended Complaint does not plead any facts to allege that the supporting facts were untrue, that Fair or Aclaris had any contrary belief, or that there was omitted information that made these opinions misleading. The survey results that accompanied Fair's statements were positive. Although those results showed that the acceptance of ESKATA was not uniform, substantial numbers of patients were pleased with the treatment. And even if those statistics and

the experience of ESKATA could have been interpreted differently, "where a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement." *Kleinman*, 706 F.3d at 154 (citing *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966-67 (D. Md. 1995) (discussing that a reasonably held opinion that is later proven wrong is, nevertheless, not actionable)). A complaint "must, and does not [here], allege more than that the speaker 'kn[e]w[], but fail[ed] to disclose, some fact cutting the other way.'" *Liu*, 2020 WL 1489831, at *11 (quoting *Omnicare*, 575 U.S. at 189).

There is no allegation that Aclaris misreported product sales or misled investors as to the commercial acceptance of ESKATA. At the same time and in the same place Fair was making these comments, Aclaris was also reporting net product sales for ESKATA. Those reports showed ESKATA net product sales of $1,533,000 for the second quarter of 2018 and $510,000 for the third quarter of 2018. *See* Vigna Decl. Exs. E, F.[10] Aclaris anticipated significant increases in sales and marketing expenses as a result of efforts to promote ESKATA. *Id.*

Other portions of the challenged statements conveyed matters of ascertainable and concrete fact that plausibly could have induced reliance by a reasonable investor. These include Fair's statements regarding ESKATA's performance and the results of the patient surveys. But Plaintiff has failed to plead facts with particularity showing that the statements were false or misleading. Indeed, Plaintiff does not allege that anything in these statements was literally false or present any facts that were omitted that were necessary to make what was said not misleading. *See Kleinman*, 706 F.3d at 153.

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[10] Because Aclaris launched ESKATA in May 2018, after the close of the first quarter of 2018, the 10-Q for the first quarter ended March 31, 2018 does not report ESKATA net product sales.

Fair and Aclaris were not under a duty to report the anecdotal experience of Aclaris sales representatives set forth in the Amended Complaint. "Disclosure of an item of information is not required . . . simply because it may be relevant or of interest to a reasonable investor." *Id.* (quoting *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002)). Fair's statements in the first quarter earnings call were limited to the results of the physician and patient surveys. Plaintiff does not dispute that Fair and Aclaris reported those results accurately nor does he contend that they omitted anything of significance from those surveys. Fair did not omit anything from the surveys that would have made his report of what the surveys said misleading. Notably, the statements made in that call on May 8, 2018 were also made the day after ESKATA was launched. *See* AC ¶ 90 ("ESKATA became commercially available [on] May 7, 2018."). They were based on information from the "limited sort of trial right now" and before ESKATA was made publicly available. Reports by the confidential witnesses submitted by Plaintiff describe patient experiences during the EEI, which "launched in the spring of 2018," but they do not put a date on whether those experiences were before or after the first quarter earnings call. *Id.* ¶ 75. The anecdotes are also limited and spread over time. Indeed, with rare exceptions, the Amended Complaint does not moor any of the confidential witness observations in time "render[ing] the task of matching CW allegations to contrary public statements all but impossible, since allegations about an unspecified time period cannot supply specific contradictory facts available to Defendants at the time of an alleged misstatement." *In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 352 (S.D.N.Y. 2011).

Moreover, there is no allegation that Fair, or anyone else in Aclaris senior management responsible for its statements, was aware of experiences of the sales representatives. Plaintiff does not allege there was any meeting at Aclaris headquarters to discuss patient results prior to

the first quarter call. At most, and without providing a timeframe, an Aclaris account specialist (CW5) stated that ESKATA's adverse effects were escalated to "senior leadership" at Aclaris, which was "completely defensive" and blew off the complaints of the sales representatives. *Id.* ¶ 78. But "[w]here plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information." *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000). Plaintiff has not done so for either confidential witness here. *See Loc. No. 38 Int'l Bhd. of Elec. Workers Pension Fund v. Am. Exp. Co.*, 724 F. Supp. 2d 447, 461 (S.D.N.Y. 2010), *aff'd sub nom. Loc. No. 38 Int'l Bhd. of Elec. Workers Pension Fund v. Am. Express Co.*, 430 F. App'x 63 (2d Cir. 2011) (allegations that confidential witness attended meetings and prepared reports for senior executives did "not establish what specific contradictory information the Individual Defendants received or when they received it") (collecting cases); *see also Plumbers & Steamfitters Loc. 773 Pension Fund v. Canadian Imperial Bank of Com.*, 694 F. Supp. 2d 287, 299 (S.D.N.Y. 2010) (allegation of "'broad reference to raw data' is not sufficient").

Even if Fair had been informed of the experience of the few sales representatives, Fair did not warrant or represent that ESKATA was painless or would remove all lesions. *See Kleinman*, 706 F.3d at 155 (defendant was not obligated to disclose that patients showed little or no improvement from drug in the short term because defendant's statements did not represent the drug had a short-term effect). Aclaris previously had disclosed the risks of ESKATA on its website and in a 2017 8-K filing. *See* Vigna Decl., Ex. O. It never described the drug as failsafe or painless. The disclosures made clear that ESKATA, like other drugs, was accompanied by side effects and did not always succeed. The fact that some patients experienced pain, there was some discoloration, and that lesions would have to be treated more than once before they were

removed did not have to be reiterated; it was not inconsistent with anything Aclaris had said in the past or said during the first quarter call. *See Kleinman*, 706 F.3d at 155-56 (statement not misleading when plaintiff did not identify a previous contrary statement creating a duty to correct). To the extent Fair spoke at all regarding skin discolorations, it was to say that 81% of patients were comfortable enough with their appearance to go out socially the day after treatment. That statement suggests that the immediate effect on appearance was an issue for all patients and that under 20% of all patients were not comfortable enough with their appearance to go out socially the day after treatment.

The same result follows with respect to the Fair's statements during the second quarter earnings call. In his comments, Fair made clear that he was basing his opinion on "the updated survey results from the early experience initiative." Vigna Decl., Ex. J. at 6. Those results—which Fair reported—made clear that a large percentage of physicians (over 80%) "indicated that applying ESKATA is easy or extremely easy," that "[o]ver 90% of patients said that ESKATA treatment application was easy and was completed in a reasonable amount of time," that "[o]ver 80% of patients indicated that the day after treatment, they were comfortable enough with their appearance to go out socially," "85% of patients said that they would recommend ESKATA treatment to their friends," and "over 90% of patients said that they would recommend ESKATA over prior treatment methods." *Id.* The results thus supported that ESKATA provided an "excellent treatment option." Those results, however, also made clear that the positive view of and experience with ESKATA was not uniform: 15% of patients would not recommend ESKATA and nearly 10% of patients believed that ESKATA was not completed in a reasonable amount of time. *See Starr ex rel. Est. of Sampson v. Georgeson S'holder, Inc.*, 412 F.3d 103, 107 (2d Cir. 2005) ("Requiring the stockholder to perform the two-minute multiplication to

ascertain the [allegedly omitted information] is not an 'omission' for which the law gives redress."). Fair's comments, read in their entirety, thus were not necessarily inconsistent with any material information that Plaintiff alleges he or Aclaris knew. For most, but not all patients, ESKATA treatment application was easy and could be completed in a reasonable period of time.

Plaintiff relies on the statement from one sales representative (CW9) who reports he had attended meetings with Fair and Walker at Aclaris's headquarters between August and October 2018in which members of the executive sales team discussed the complaints sales representatives had received from physicians and patients about "adverse side effects and complaints that ESKATA was not effective." AC ¶ 98. The meeting was after the first quarter earnings call (and so cannot support Plaintiff's allegations with respect to that call) and at or after the time of the second quarter earnings call. The allegations do not support the claim that the statements on the second quarter earnings call were false or misleading. The complaints that CW9 claims to have heard and that were reported were that "ESKATA was ineffective because it took many more applications to achieve any results than the physicians had been told when they were sold the product." *Id.* Those allegations are not inconsistent with the statements made by Fair in the second quarter earnings calls. All that Fair disclosed was the general positive feedback and that over 96%, and later 90%, of patients said the treatment "was completed in a reasonable amount of time." The comment was about patient acceptance of the product. He made no statements about whether those reasonable number of treatments was consistent with what each physician had expected when he or she was initially sold the product.

Moreover, even if the experiences of the Aclaris confidential witnesses were known to Aclaris executives prior to the allegedly misleading statements, they constitute no more than "a handful of anecdotal reports." *Matrixx*, 563 U.S. at 45. Plaintiff offers undated testimony from

3 of 50 sales representatives, one sales manager, and one account specialist; Plaintiff offers no reason to believe that these experiences were representative of the experience of all or even a meaningful number of patients. The sales representatives did not say that ESKATA never worked; they said it did not always work. As to the reviews posted on the internet, the statements during the second quarter earnings call were made on August 3, 2018, which was prior to all but one of the reviews posted on the internet, and either at or shortly before the time of the meeting at Aclaris's headquarters pleaded by Plaintiff. The one internet review that preceded those statements, which was posted on May 7, 2018, said that "[a]fter one treatment none of my SK was gone." AC ¶ 90. But that one review does not suggest that all patients had that experience, or that Defendants knew that they did. *Cf. Montich v. Miele USA, Inc.*, 2013 WL 5523689, at *7 (D.N.J. Sept. 30, 2013) ("Random anecdotal examples of disgruntled customers posting their views on websites at an unknown time is not enough to impute knowledge upon defendants.") (quoting *Oestreicher v. Alienware Corp.*, 544 F. Supp. 2d 964, 975 n.9 (N.D. Cal. 2008)). Moreover, the statement, that "[a]fter one treatment none of my SK was gone, does not contradict Fair's statements that "we're getting a lot of positive feedback," or "85% of patients said that they would recommend ESKATA treatment to their friends." Nor does it render false the statement that "the product really works" as Aclaris had said that with ESKATA, the raised SK goes away "typically in one or two treatments." AC ¶ 109. Plaintiff does not point to any statements made by Fair regarding efficacy or how many treatments were required before ESKATA was effective. It was not necessary for Fair to state that some patients would not recommend ESKATA to friends or that the treatment was not effective for everyone. The statistics which he disclosed themselves revealed that information.

Finally, Fair's comment in the second quarter earnings call, that the "product really works," was also accompanied by language that made clear that ESKATA worked only with the right patients and right lesion types and that it did not always work.[11] *See* Vigna Decl., Ex. J. at 17-18. Both viewed in isolation and viewed in the context of other statements made by Fair during the call, it cannot be understood as a statement that it always and invariably worked. Fair stated: "[I]f you rub it in too hard or if they go too aggressive with it, you can get some edema and you can get some redness associated with it that" and that the sales representatives were scheduling re-trainings with physicians to "make sure [they]'re focusing on the right lesions and the right patient types" and so that the physicians knew "how [to] apply the product." *Id.* He continued: "[O]ther than that, I think people are pretty excited about the response that they're getting with the treatment. . . . You don't have a lot of edema and crusting and bleeding that you do with some of the other procedures they're currently using. So a lot of them are seeing it and just really liking it. . . . [I]t's about trying to get them to connect it to the right patients in the practice." *Id.* In other words, Fair qualified his statement both by making clear that there were instances in which ESKATA did not work and by indicating that his comment was relative, i.e., the product performed better than the alternatives. *See In re Synchrony*, 988 F.3d at 171-72 (distinguishing comments that are binary from those that are qualitative). His comments also came against a backdrop of information in the market regarding ESKATA's effectiveness.

[11] Plaintiff alleges incorrectly that the statement was made in response to an analyst question about "what sort of pushback [Aclaris was] getting from some of the doctors." AC ¶ 132; Vigna Decl., Ex. J at 17. The statement was made in response to a request for "an anecdote on how much [doctors are] willing to embrace [the] new product" and "how excited they are and that sort of thing." Vigna Decl., Ex. J at 17-18. Whether doctors are "excited" about Aclaris is different from whether doctors gave "pushback"—a separate concept that has been recently defined by the Second Circuit in a securities fraud case as "resistance or opposition in response to a policy or regulation especially by those affected," or as a "negative reaction to a change or to something new that has been introduced." *In re Synchrony*, 988 F.3d at 168 (citations omitted).

Viewed in context, Fair's statements were not inconsistent with the actual experience patients had with ESKATA as of May 2018 and then August 2018 as alleged by Plaintiff. No reasonable investor would have understood the statements to indicate that there were no patients who experienced pain, that ESKATA was always successful in removing lesions, or that there was the possibility of skin discoloration.

2. Statements Regarding the DTC Campaign and "The View"

Plaintiff's second set of allegations relate to the DTC campaign and to the comments made about "The View" segment. Plaintiff challenges the following statements by Fair made during the second quarter earnings call on August 3, 2018:

- During Fair's introductory remarks: "With regards to DTC, we have filmed the ESKATA TV commercial and plan to air the commercial beginning in October. The ESKATA TV commercial is part of a comprehensive consumer campaign that includes both print and digital media with the goal of driving SK awareness and treatment with ESKATA. *Our consumer campaign will encourage patients to see their dermatologist and/or go to eskata.com to find a provider near them.*" AC ¶ 142; Vigna Decl., Ex. J at 6;

- In the same call, Fair's response to an analyst question about sales progression and the ramp-up for ESKATA in light of the DTC campaign: "So right now, we're focused on driving clinical integration between now and DTC in October. *We think we're in a good place. I think we'll be in a very good place come the time we activate DTC.* And I think that's when you'll start seeing it really start picking up." AC ¶ 143; Vigna Decl., Ex. J at 11.

Plaintiff also challenges the following statements by Fair made during the third quarter earnings call on November 6, 2018:

- During Fair's introductory remarks: "*We believe our DTC, PR efforts, such as our most recent spot on The View*, will also help drive interest as patients are directed to the Find A Doctor page on the ESKATA website." AC ¶ 144; Vigna Decl., Ex. K at 7;

- In the same call, Fair's response to an analyst question about whether Aclaris is happy with the DTC program thus far and "any quantification around that would be helpful": "In terms of the ESKATA DTC metric, it's very early so it's initiated in October, there's a lag in terms of seeing the impact of doing DTC. But we've seen a big spike in, obviously, in the website traffic results over the course of October, *so*

> *big spike with The View. And then we've seen a big spike continue to grow in the month of October, that's a good sign.*" AC ¶ 144; Vigna Decl., Ex. K at 13-14.

Plaintiff alleges that these statements were misleading because they failed to disclose that the DTC campaign and "The View" segment, which were the primary drivers of physician and patient interest in ESKATA, misrepresented the risks and efficacy of ESKATA in violation of the FFDCA. AC ¶ 145. In making these misrepresentations, Defendants concealed the risk that ESKATA was not commercially viable and could only be effectively marketed using materials that misrepresented its risks and efficacy; thus once the truth regarding ESKATA was revealed, it was discontinued, which drove down the value of Aclaris's stock. *Id.*

The securities laws cannot be used as a backdoor to require a company, as a matter of routine, to disclose every regulatory warning or letter it receives. "[I]n the absence of an express prior disclosure, a corporation has no affirmative duty to disclose 'uncharged, unadjudicated wrongdoing.'" *DoubleLine Capital LP v. Odebrecht Finance, Ltd.*, 323 F. Supp. 3d 393, 441 (S.D.N.Y. 2018) (quoting *City of Pontiac v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014)). But a duty to disclose "can arise when a corporation puts the reasons for its success at issue, but fails to disclose that a material source of its success is the use of improper or illegal business practices." *Id.* (quoting *Menaldi v. Och-Ziff Capital Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 581 (S.D.N.Y. 2016)). That duty arose here when Defendants attributed the expected success of ESKATA to the DTC campaign and highlighted, in particular, the advertising contained on "The View."

The Amended Complaint plausibly alleges that FDA OPDP sent Aclaris a letter in March 2018 indicating that advertising statements—such as those which were later included in "The View" segment—"omit[ted] material information regarding the risks associated with Eskata or otherwise misrepresent[ed] important risk information" or "overstate[d] the efficacy of Eskata." Vigna Decl., Ex. N at 2. It also plausibly alleges that the March 2018 Letter addressed "draft

Aclaris presentations for Eskata with certain similarities to [“The View” segment]” and “direct[ed]” Aclaris not to make such misrepresentations in the future. *Id.* It further plausibly alleges facts that, notwithstanding that direction from FDA, Aclaris decided nonetheless—and with knowledge that they were violating the FDA letter—to proceed with the representations that the FDA believed to be misleading. *See, e.g.*, AC ¶¶ 113, 124-28, 141-45. Finally, and critically for purposes of a securities fraud case, Plaintiff alleges that after Defendants decided to proceed with a marketing campaign that they knew was believed by the FDA to be misleading and that the FDA would attempt to enjoin if it found the campaign to be misleading, Defendants touted that campaign as the source of ESKATA’s likely future success.[12]

The fact that the FDA had communicated to Aclaris that its advertising materials omitted material information regarding ESKATA’s risks or overstated ESKATA’s efficacy was not merely incidental or insignificant to Fair’s message regarding the DTC campaign. At the time of these statements, Aclaris was a single drug company. Aclaris’s marketing was central to the product’s acceptance by patients and physicians and to the product’s success. “The View” was the centerpiece of Aclaris’s DTC campaign, and as suggested by Aclaris, how ESKATA was portrayed on “The View” would be critical to ESKATA’s success and therefore Aclaris’s success as a company. *See Schaeffer v. Nabriva Therapeutics plc*, 2020 WL 7701463, at *9 (S.D.N.Y. Apr. 28, 2020) (interim feedback from the FDA, which observed that a defendant’s manufacturing plant might not be in compliance, “suggested the FDA might deny marketing approval for [a drug candidate] if [defendant] did not address the [] observations in time, which would plainly impact [defendant]’s profitability in the eyes of a reasonable investor”).

[12] Plaintiffs do not challenge the DTC campaign itself, but rather statements about the DTC campaign that were made to shareholders.

Although the initial success and interest of ESKATA "may well have been due to" non-DTC campaign-related factors, such as patient and physician satisfaction with the product, Plaintiff plausibly alleges "an ordinary investor would be misled by the company's failure to disclose," when promoting the marketing campaign to investors, "that an additional reason for its success" were misrepresentations made about ESKATA in that marketing campaign. *DoubleLine*, 323 F. Supp. 3d at 444 (collecting cases). In the second quarter earnings call, before "The View" segment aired, Fair attributed the growing interest in and expected success of ESKATA to the DTC campaign. In the third quarter earnings call, after "The View segment aired, Fair attributed the "big spike" in the website traffic to the DTC campaign and "The View," and created the impression that, after a lag, that spike would lead to increased sales of Aclaris's largest product. It is thus not sufficient for Defendants to respond that Fair's statement concerning the "big spike" in website traffic following "The View" segment was literally true or that his other statements were mere predictions future interest in ESKATA without attribution of such interest to any particular cause. *See Gagnon v. Alkermes PLC*, 368 F. Supp. 3d 750, 768-69 (S.D.N.Y. 2019); *see also Das v. Rio Tinto PLC*, 332 F. Supp. 3d 786, 808 (S.D.N.Y. 2018) ("[A] company's statements become actionable if the company attributes its success to a particular cause without also disclosing the unlawful activity that contributed to that success.").

The allegations are equivalent to those courts have sustained where a company reports positive sales results without disclosing that those results were due, even if in part, to bribery, antitrust violations, or some other illegal conduct. *See DoubleLine* 323 F. Supp. 3d at 441-43 (defendant failed to disclose that its success was due, in part, to an illegal bribery scheme); *In re Mylan N.V. Sec. Litig.*, 2018 WL 1595985, at *7 (S.D.N.Y. Mar. 28, 2018) (defendant failed to disclose it was engaged in anticompetitive efforts while discussing the competitive market);

Gagnon, 368 F Supp. 3d at 768 (defendant failed to disclose that increasing sales were due to deceptive marketing and lobbying efforts).

Defendants make two further arguments about the DTC campaign. First, they claim that because Defendants did not discuss regulatory compliance when they talked about the DTC campaign, they were no under an obligation to disclose that the campaign had used statements that the FDA claimed to be misleading. That argument, however, runs squarely into the holdings of a long line of cases that found a duty to disclose even where the defendant made no statement about regulatory compliance when speaking about the company's success. *See DoubleLine*, 323 F. Supp. 3d at 444; *In re VEON Ltd. Sec. Litig.*, 2017 WL 4162342, at *6-7 (S.D.N.Y. Sept. 19, 2017); *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 400-01 (S.D.N.Y. 2005); *In re Par Pharm., Inc Sec Litig.*, 733 F. Supp. 668, 675, 677-78 (S.D.N.Y. 1990); *see also City of Brockton Ret. Sys. v. Avon Prod., Inc.*, 2014 WL 4832321, at *18 (S.D.N.Y. Sept. 29, 2014). The holdings of those cases turned upon the notion that when a company discloses certain of the reasons for its success that are the result of legal activities, it cannot withhold the reasons for that success that are illegal or improper.

Second, Defendants argue that Plaintiff has not stated a claim because he has not alleged that Aclaris actually violated any marketing regulations. The Second Circuit addressed a closely-related question in *Gamm v. Sanderson Farms, Inc.*, 944 F.3d 455 (2d Cir. 2019) in which plaintiffs alleged that the defendant, a poultry processing company, violated the federal securities laws by failing to disclose it was engaged with its competitors in a conspiracy to restrain trade in the poultry market. The Second Circuit stated that "when a complaint claims that statements were rendered false or misleading through the non-disclosure of illegal activity, the facts of the underlying acts must be pleaded with particularity, in accordance with the

heightened pleading requirements of Rule 9(b) and the PSLRA." *Id.* at 465. The Second Circuit thus held that where the alleged illegal conduct is an antitrust conspiracy, "the pleading standard required [plaintiffs] to have alleged the basic elements of an underlying antitrust conspiracy." *Id.* at 466; *see also id.* at 466-67. It did not require plaintiffs to plead that defendants had admitted to the conspiracy or been convicted of it.

There are two answers to Defendants' argument. First, the Amended Complaint can be read to plausibly allege that Defendants did not just omit that they were engaged in illegal activity but also that the FDA had directed them not to engage in that activity and that they were therefore on notice that if Aclaris launched and continued the DTC campaign as it had been doing and planned, the FDA would bring an action for Aclaris to cease that campaign. Thus, the misleading nature of the omission stands apart from the question of whether Aclaris actually was violating the law. The omitted information—of the position that the FDA had taken and the Company's decision to proceed notwithstanding that position—was necessary to make what was said not materially misleading, regardless of whether the FDA's position ultimately would prevail. *See Gordon v. Vanda Pharm. Inc.*, 2021 WL 911755, at *3 (E.D.N.Y. Mar. 10, 2021) (statements regarding the company's marketing practices, which failed to convey that the company's suspect drug promotion activities had not been approved by FDA, were misleading); *In re Mylan*, 2018 WL 1595985, at *13 (misclassification statements were misleading where defendant knew the product was misclassified because federal agencies had identified the product as a misclassified drug and provided guidance on how to correct it).

Second, the standards of *Gamm* are satisfied here. The FFDCA prohibits the making of false or misleading claims and/or representations about the risks associated with and the efficacy of pharmaceuticals and medical devices. *See* 21 U.S.C. §§ 352(a), (n); 21 U.S.C. § 321(n); 21

U.S.C. § 331(a). The FDA sent Defendants a letter in March 2018, identifying that Aclaris's advertising materials omitted material information regarding ESKATA's risks and efficacy and directing that changes be made. *See* Vigna Decl., Ex. N. When Defendants apparently failed to make such changes, the FDA sent Defendants a second letter in June 2019, which informed them that they were in violation of the FFDCA and instructed them to cease such violations or, if Defendants disagreed, to submit a response challenging the FDA's finding. That June 2019 Letter made reference to the March 2018 Letter, which the FDA said had warned Aclaris about similar omissions they had made in presentations for ESKATA. At this stage, Plaintiff has alleged the basic elements of the underlying offense.

The cases upon which Defendants rely are inapposite. In *In re Sinclair Broadcast Grp., Inc. Sec. Litig.*, 2020 WL 571724 (D. Md. Feb. 4, 2020), the district court dismissed a claim that the defendant's report of its revenues was false and misleading because defendant did not disclose it was engaged in a price-fixing conspiracy on the basis that the complaint did not allege with particularity "the basis for the illegality." *Id.* at *19. In passing, the district court stated that "[t]he unproven allegations in the DOJ complaint do not establish illegality, nor does the fact that [defendant] reached a non-punitive settlement with the DOJ." *Id.* at *20. That finding was due, in part, to the fact that the underlying allegations as to whether the company was engaged in a price-fixing conspiracy were disputed and the plaintiffs had pleaded no facts to establish illegal conduct. *See, e.g., id.* ("None of th[e] CWs . . . describe any concrete examples of conduct consistent with an illegal price-fixing scheme.").[13] Here, by contrast, Plaintiff pleads far more

[13] *Highfields Capital I, LP v. SeaWorld Entm't, Inc.*, 365 F. Supp. 3d 1050 (S.D. Cal. 2019), is even farther afield as that case did not involve the failure to disclose uncharged, unadjudicated improper conduct. Plaintiffs' argument was merely that the district court should find that the complaint stated a claim because the SEC filed a parallel enforcement lawsuit that was settled without admitting or denying liability. The district court held that plaintiffs could not plead their

than that the FDA accused Defendants of engaging in false and misleading advertising. He pleads, with particularity, that Defendants did engage in false and misleading advertising, including by identifying the advertising at issue and what made it false and misleading.[14] The landscape may look different at summary judgment, when the March 2018 Letter and the correspondence and conversations around it are disclosed, but for now Plaintiff has pled actionable misstatements.

3. Statements Regarding Sales of ESKATA

Plaintiff alleges that during Aclaris's third quarter earnings call on November 6, 2018, Walker misrepresented the cause of the decline in sales of ESKATA. During that call, Walker stated:

> I think what we thought when we envisioned this out of the gate was that we would be treating about 2—we'd be meeting 3 patients about 2x, 3x based on the number of lesions they have and the location on the body. And I think what we're finding is that we're clearing lesions a lot quicker, 1x to 2x. And that's kind of good and

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claim with particularity solely by relying on the allegations in the SEC complaint, which were unproven. *Id.* at 1057 & n.2.

[14] Defendants also challenge the FDA's conclusion that Aclaris violated the FFDCA on the theory that Aclaris's marketing materials could not be materially misleading as to ESKATA's side effects and efficacy based on ESKATA's public label and an academic article published in the Journal of the American Academy of Dermatology on June 1, 2018 discussing the full results of ESKATA's Phase 3 trials (the "JAAD Article"). But the FDA took into account the existence and availability of that information when it still found that "The View" segment, and draft presentations with similarities to "The View" segment, was materially misleading. It acknowledged that in the video segment, the "Physician Spokesperson referr[ed] consumers to Eskata.com for more information" and that "the video include[d] superimposed text (SUPERs) listing the drug's most common side effects and directing consumers to Eskata.com for fully safety and prescribing information." Vigna Decl., Ex. N at 2; *see also id.* at 4. "However," it stated, these disclosures still did "not mitigate the video's omission of the serious risk information regarding the warnings and precautions about serious eye disorders that can result from unintended exposure and about severe local skin reactions." *Id.* at 2. In other words, the FDA rejected the argument that a consumer's access to information about ESKATA's side effects and efficacy elsewhere would prevent "The View" segment at issue and "certain similar" presentations from being materially misleading.

> bad. I think we're getting a little bit more robust response, but sometimes that results in a little bit of a brisker reaction.

AC ¶ 139; *see* Vigna Decl., Ex. K at 13.

Plaintiff does not dispute that this statement was literally true. Initially, Aclaris expected that physicians would see patients on average 2-3 times based on the number of lesions they had and their location on the body; the actual experience was that physicians only needed to see patients 1-2 times in order to clear the lesions. Plaintiff alleges, instead, that the statement is false by omission. According to Plaintiff, the statement implies that ESKATA's decline in sales was a result of the quicker clearance of lesions and thus the statement was misleading because it failed to disclose that the real reason that sales were "poor" was because ESKATA was limited in effectiveness, painful, and left skin discolorations. AC ¶ 140.

Plaintiff's allegation fails in two independent respects. First, Walker's statement cannot be read to state or reasonably imply that ESKATA's sales were a function of the number of times a physician had to see a patient in order to clear lesions. In judging how a statement could be read by a reasonable investor, the Court considers the context in which the statement was made. *See, e.g.*, *Jinkosolar*, 761 F.3d at 250 ("The literal truth of an isolated statement is insufficient; the proper inquiry requires an examination of defendants' representations, taken together and in context."). Here, Walker's statement was made in response to a question regarding "the doctor experience with ESKATA," specifically, whether there was a "change in the traditional experience versus the initial phases of the launch." Vigna Decl., Ex. K at 13. The question was directed to physician acceptance and experience with the product and not to its sales. Walker's response, in turn, addressed the physician experience and the lag between the time physicians first use ESKATA and the time they give ESKATA to staff to administer to patients. *See id.* ("And that's one of the biggest lags. And we mentioned this in our last call, it's just that kind of

time period between the initial trial of the product, which can take up to a couple of months and then just putting it into their flywheel, and really start accelerating that.”). That question did not speak to, and was not even necessarily relevant to, the cause of decreased sales of ESKATA. The sales of ESKATA presumably are a function of the number of patients who are prescribed or receive ESKATA *and* the number of treatments a patient would need to receive. The fact that physicians needed to see patients fewer times than initially expected did not necessarily imply that, as a result, Aclaris's sales would decline. Sales could just as easily increase if more patients were advised to use ESKATA. Walker's statement did not speak to the actual sales results, it spoke to the actual physician experience as compared to the expected physician experience. Plaintiff thus mischaracterizes Walker's statement when it argues that “Defendants assured analysts on the Q3 2018 Call in November 2018 that slow sales were because ESKATA was ‘clearing lesions a lot quicker.’” Dkt. No. 45 at 16.

Second, even if Walker's statement could be read to be one regarding ESKATA's sales, Plaintiff has not pled facts demonstrating that the statement was false. *See Rombach*, 355 F.3d at 174 (“[P]laintiffs must do more than say that the statements in the press releases were false and misleading; they must demonstrate with specificity why and how that is so.”). In other words, Plaintiff has not pled that at the time the statement was made, ESKATA sales were declining due to problems regarding ESKATA's effectiveness and its safety. Nowhere does the Amended Complaint plead facts, whether possessed by Walker or otherwise, that Aclaris's declining sales were due to these problems; the link between the anecdotal evidence from patient surveys and the declining sales is too conclusory. *See* AC ¶¶ 12-14; *cf. In re Synovis Life Techs., Inc. Sec. Litig.*, 2005 WL 2063870, at *11 (D. Minn. Aug. 25, 2005) (plaintiffs “failed to plead the particularized who, what, where, when and how necessary to show” statements were false).

Moreover, once Aclaris disclosed the declining sales numbers, Defendants "were under no duty to characterize that information in a particular way." *Abuhamdan v. Blyth, Inc.*, 9 F. Supp. 3d 175, 200 (D. Conn. 2014); *see also In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 403-04 (S.D.N.Y. 2016) (description of sales growth not actionable where it "did nothing more than characterize, albeit [] with more fanfare, the statistical facts . . . that diabetes product sales were growing"). Nor can Plaintiff rely on the fact that Aclaris later announced it was discontinuing ESKATA due to its insufficient sales; such an allegation constitutes classic fraud by hindsight. *See In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014), *aff'd*, 604 F. App'x 62 (2d Cir. 2015) ("A statement believed to be true when made, but later shown to be false, is insufficient."); *see also Novak*, 216 F.3d at 309 (fraud by hindsight is not actionable).

4. Statements Regarding Risk Factors

Plaintiff alleges that Aclaris's failure to disclose that the DTC campaign was misleading as to ESKATA's risks and efficacy also rendered misleading certain of Aclaris's risk factors in its quarterly and annual statements filed with the SEC because they failed to disclose that the DTC campaign had already violated federal law. AC ¶¶ 146, 151. Specifically, he points to the risk factor that: "ESKATA, or any drug candidate for which we obtain marketing approval, could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates, when and if any of them are approved." *Id.* ¶ 147; Vigna Decl., Ex. D. The risk factor went on to state: "Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to

investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws." *Id.*[15]

"Courts in this Circuit have held that a company's purported risk disclosures are misleading where the company warns only that a risk may impact its business when that risk has already materialized." *In re Coty Inc. Sec. Litig.*, 2016 WL 1271065, at *11 (S.D.N.Y. Mar. 29, 2019); *see In re Facebook, Inc. IPO Sec. & Derivative Litig.*, 986 F. Supp. 2d 487, 516 (S.D.N.Y. 2013) ("The Company's purported risk warnings misleadingly represented that this revenue cut was merely possible when, in fact, it had already materialized."); *see also Rombach*, 355 F.3d at 173 ("Cautionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired."). But contrary to Plaintiff's claim, the risks that Plaintiff emphasizes had not materialized at the time of the SEC filings, or even later.

Neither the March 2018 Letter nor the June 2019 Letter imposed post-marketing restrictions. As the full text of the risk disclosure makes clear, "restrictions on the labeling or marketing of a drug" referred to a "limit [in] the approved use of our drug, which could limit sales of the drug" or "restrictions on manufacturers' communications regarding off-label use." Form 10-K at 51-52 (December 31, 2017). Neither the March 2018 Letter nor the June 2019 Letter recommended or imposed limitations on the approved use of ESKATA or on the advertising regarding off-label use. *See In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 365-66 (2d Cir. 2010) (when analyzing "materials for compliance with the securities laws,

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[15] This risk factor was in the 2017 10-K. The 2018 10-K contained the identical risk factor. AC ¶ 149; Vigna Decl., Ex. G. The 10-Qs for the second and third quarters of 2018 for the periods ended June 30, 2018 and September 30, 2018, respectively, stated that the risk factors had not changes since the 2017 10-K, AC ¶ 148; Vigna Decl., Exs. E-F, and the 10-Qs for the first and second quarters of 2019 for the periods ended March 31, 2019 and June 30, 2019 respectively, stated that the risk factors had not changed since the 2017 10-K, AC ¶ 150; Vigna Decl., Ex. H.

we review the documents holistically and in their entirety. . . The literal truth of an isolated statement is insufficient; the proper inquiry requires an examination of "defendants' representations, taken together and in context"); *Rombach*, 355 F.3d at 172 n.7 (whether a statement is materially misleading turns on "whether the defendants' representations, taken together and in context, would have misled a reasonable investor"). The letters also did not require ESKATA's post-marketing "recall or withdrawal from the market," did not impose "penalties," and had not resulted in Aclaris facing "investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws." The FDA stated in the March 2018 Letter and June 2019 Letter that Aclaris's advertising materials omitted material information regarding ESKATA's risks or overstated ESKATA's efficacy. It recommended and directed—and in the case of the June 2019 Letter, required—that Aclaris change those materials, but imposed no further sanctions, and Plaintiff has not alleged that Aclaris faced other investigations.[16]

Thus at the time that the risk factors were issued, the risk that noncompliance with the FFDCA would result in post-marketing restrictions, recall, or withdrawal from the market, penalties, or investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws "had neither 'transpired' nor become a 'near

[16] Earlier in this opinion, the Court held that, in connection with Fair's statements about the DTC campaign's success, Defendants had a duty to disclose that it had been warned that the FDA suggested that the DTC campaign had misrepresented the risks and efficacy of ESKATA in violation of the FFDCA. *See supra*. That duty to disclose arose because in those statements, Aclaris had "put[] the reasons for its success at issue, but fail[ed] to disclose that a material source of its success is the use of improper or illegal business practices." *DoubleLine*, 323 F. Supp. 3d at 441 (quoting *Menaldi*, 164 F. Supp. 3d at 581). In contrast to Fair's statements regarding the DTC campaign, these risk disclosures do no such thing.

certainty'" even if the "alleged noncompliance had occurred." *In re FBR Inc. Sec. Litig.*, 544 F. Supp. 2d 346, 362 (S.D.N.Y. 2008) (quoting *Rombach*, 355 3d at 173).

5. SOX Certifications

Plaintiff challenges that Defendants' SOX certifications appended to each of Aclaris's quarterly and annual SEC filings were false or misleading. Those certifications were signed by Aclaris's CEO and CFO, Walker and Ruffo, and represented that the filings did not contain any untrue statement of material fact or omissions necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report. AC ¶¶ 152, 154. Plaintiff alleges that these certifications were misleading because they failed to disclose that (1) Defendants were promoting ESKATA to patients using advertising materials that were misleading; (2) as a result, Aclaris was likely to face regulatory scrutiny; and (3) as a result of the foregoing, the statements about Aclaris's business, operations and prospects were materially misleading. *Id.* ¶ 156.

The law in this District is clear and uniform that such SOX certifications do not provide a stand-alone basis for liability. Either the SEC filings contain materially misleading statements (in which case those statements can form the basis for liability) or they do not contain such statements. An allegation that the certification is false and misleading adds nothing. *See In re Glob. Brokerage, Inc.*, 2019 WL 1428395, at *14 (S.D.N.Y. Mar. 28, 2019) ("SOX certifications do not 'constitute a standalone basis for liability.'") (quoting *Menaldi v. Och-Ziff Cap. Mgmt. Grp. LLC*, 277 F. Supp. 3d 500, 517 (S.D.N.Y. 2017)).

The only alleged misstatements or omissions that Plaintiff points to in the SEC filings are the risk factors. But, as discussed, Plaintiff failed to adequately plead that there were material misstatements or omissions in those risk factors. Absent any material misstatements or

omissions in Aclaris's SEC filings, Defendants cannot be liable through their SOX certifications. *See Chapman*, 466 F. Supp. 3d at 410.

B. "Makers" of the Statements

Defendants move to dismiss claims against Aclaris's Chief Legal Officer, Ali-Jackson, because she did not make any of the alleged misstatements. Plaintiff responds that Ali-Jackson is a maker of the statements in the SEC filings because a high-level executive who plays a daily role in the company's operations is said to "make" statements in the company's group published written filings. *See City of Pontiac General Empls.' Ret. Sys. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 373 (S.D.N.Y. 2012).

Assuming the group pleading doctrine survives *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135, 142 (2011), it applies only to written documents, not to oral statements. *See, e.g.*, *Das*, 332 F. Supp. 3d at 805. The only written documents that Plaintiff challenges are the SEC filings that Ali-Jackson did not sign and which this Court has held are not actionable.[17] There can be no Section 10(b) liability against Ali-Jackson, or against Walker and Ruffo who also did not make the alleged misstatements on the quarterly earnings calls.[18]

C. Scienter

"The requisite scienter [in a securities fraud case] can be established by alleging facts to show either (1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." *ECA*, 553 F.3d at 198. To establish a motive and opportunity, "plaintiffs must assert a concrete and personal benefit" to the individuals who allegedly carried out the fraud. *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir.

[17] Plaintiff does not challenge the script used for "The View" segment, which they allege Ali-Jackson to have edited, as a misstatement. AC ¶ 115.
[18] The Court need not address whether the group pleading doctrine survives *Janus*, which would still not change the result here.

2001). A plaintiff can establish scienter in the absence of motive, but "the strength of [plaintiff's] circumstantial allegations must be correspondingly greater." *ECA*, 553 F.3d at 199 (quoting *Kalnit*, 264 F.3d at 142).

Plaintiff does not attempt to plead motive and opportunity, nor could he, as "[t]he absence of stock sales by insiders, or any other evidence of pecuniary gain by company insiders at shareholders' expense, is inconsistent with an intent to defraud shareholders." *In re N. Telecom Ltd. Secs. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000); *see also ECA*, 553 F.3d at 198 ("Motives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation do not constitute 'motive' for purposes of this inquiry.").

Plaintiff instead relies on a theory of recklessness, which is defined as, "at the least, conduct which is 'highly unreasonable' and which represents 'an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.'" *Novak*, 216 F.3d at 308 (quoting *Rolf v. Blyth, Eastman Dillon & Co., Inc.*, 570 F.2d 38, 47 (2d Cir. 1978)). In addition, an "egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference of recklessness." *Id.* (quoting *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996)). "At least four circumstances may give rise to a strong inference of the requisite scienter: where the complaint sufficiently alleges that the defendants (1) 'benefitted in a concrete and personal way from the purported fraud'; (2) 'engaged in deliberately illegal behavior'; (3) 'knew facts or had access to information suggesting that their public statements were not accurate'; or (4) 'failed to check information they had a duty to monitor.'" *ECA*, 553 F.3d at 199 (quoting *Novak*, 216 F.3d at 311).

Plaintiff has met this bar with respect to statements regarding the DTC campaign and advertising of ESKATA by alleging that Defendants "knew facts or had access to information suggesting that their public statements were not accurate." *Id.* Plaintiff alleges, through CW2 who was the vice president of pharmaceutical development and manufacturing until September 2018, AC ¶ 44, that Aclaris's "senior leadership team, including the Individual Defendants, were involved in all aspects of bringing ESKATA to market and would have been aware of the substance of any communications to or from the FDA," *id.* ¶ 124. That senior leadership team included Fair as Chief Commercial Officer, who was considered an executive officer of the Company. *Id.* ¶ 40. CW7, the former executive director of medical affairs, also stated that concerns about whether Aclaris's marketing materials and other publications were making misleading statements about ESKATA's safety and effectiveness were debated at PRC meetings, and that any concerns not settled by Ali-Jackson, including concerns CW7 himself had raised, were escalated to Walker, Ruffo, and Fair. *Id.* ¶¶ 125-26. CW7 personally attended meetings with Defendants Ali-Jackson, Walker, Ruffo and Fair that were held due to concerns about misleading claims about ESKATA's effectiveness and risks that had been raised during prior PRC meetings. *Id.* ¶ 126. Finally, CW7 states the script for "The View" segment was escalated to Fair and other senior leadership after it was debated in PRC meetings. *Id.* ¶ 115. Taken together, these allegations, if true, would give rise an inference that Fair and the other Defendants had access to the FDA letters and were aware of internal concerns about misleading marketing. That scienter is imputed to Aclaris. *See Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008); *In re Parmalat Sec. Litig.*, 594 F. Supp. 2d 444, 451 (S.D.N.Y. 2009).

Defendants repeat their claim that Fair did not know Aclaris was violating any FDA regulations because "Plaintiff merely alleges [the March 2018 Letter] contained 'advisory comments' that 'recommended' Aclaris revise certain proposed presentations" and "Plaintiff does not allege the letter accused Aclaris of violating the FFDCA." Dkt. No. 38 at 22-23. But that assertion fails to accept the allegations of the Amended Complaint, as the Court is required to do on this motion to dismiss. The Court does not have the March 2018 Letter before it. Plaintiff presumably does not have it and Defendants chose not to attach it to their motion to dismiss. *See* AC ¶ 18. What the Court has is the description of that March 2018 Letter in the FDA's June 2019 Letter. In that letter, the FDA—describing its own prior letter—stated it had warned that Aclaris was "promoting Eskata in a manner that fails to adequately present the serious risks of the drug or describe the efficacy of the drug in a truth and non-misleading manner," and directed that Aclaris stop doing so. Vigna Decl., Ex. N at 2. The letter further indicated that Defendants' failure to correct those advertising materials "despite this direction from OPDP" resulted in the June 2019 Letter, which found that Aclaris was violating the FFDCA. Accepting those allegations as true, as the Court must at this stage, the March 2018 Letter specifically warned that representations of the type Defendants made in the DTC campaign were misleading and that if Defendants continued to make those representations, the FDA would demand that Aclaris cease doing so.

Defendants also claim that, with respect to CW7, Plaintiff at most contends that there were differing views as to whether Aclaris's marketing materials were adequate and "differences of opinion, even stark differences, between employees do not reveal scienter." *City of Austin Police Ret. Sys. v. Kinross Gold Corp.*, 957 F. Supp. 2d 277, 299 (S.D.N.Y. 2013). The argument again fails to grapple with the specific factual allegations of the Amended Complaint.

Plaintiff alleges here that Defendants knew that the advertising would run afoul of concerns previously expressed by the FDA in the letters and decided to tout the expected success of that advertising nonetheless. Plaintiff alleges not only that concerns regarding the marketing were communicated to the Individual Defendants, including Fair, but also that the Individual Defendants were notified of the specific reasons why the marketing was considered to be misleading—and that communication was bolstered by the FDA's March 2018 Letter.

The cases upon which Defendants rely are distinguishable. In *City of Austin*, the plaintiff alleged that statements made by the defendants regarding the adequacy of their due diligence were known to be false because former employees had expressed the view that that the defendant company's due diligence was inadequate. The court held that those post hoc allegations were inadequate to allege scienter because plaintiff had not alleged that those concerns about due diligence had been communicated to defendants or that defendants were aware of specific facts showing their statements to be false. *Id.* at 299-300. Similarly, in *In re Pretium Resources Inc. Securities Litigation*, 256 F. Supp. 3d 459, 481 (S.D.N.Y. 2017), *aff'd sub nom. Martin v. Quartermain*, 732 F. App'x 37 (2d Cir. 2018), the court held that the "difference of opinion" between a defendant company and its consultant concerning the potential for economic success of a mining and exploration project did not reveal scienter. Plaintiffs alleged that the company's forecasts of the project's success were misleading because the underlying data collected by the consultant did not support the forecasts and the consultant did not believe the project would be economically viable. The court rejected these arguments as a mere difference of opinion because plaintiffs did not "identify with specificity the documents or way in which this contrary information was communicated" to defendants as the consultant had never finished its report with the underlying data and plaintiffs had failed to allege how or when that data was

communicated to defendants. *Id.*; *see id.* at 82; *see also Ret. Bd. of Policemen's Annuity & Benefit Fund of Chicago on behalf of Policemen's Annuity & Benefit Fund of Chicago v. FXCM Inc.*, 333 F. Supp. 3d 338, 352 (S.D.N.Y. 2018), *aff'd*, 767 F. App'x 139 (2d Cir. 2019) (rejecting scienter for similar reasons). Finally, in *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372, 417 (S.D.N.Y.), *aff'd*, 757 F. App'x 35 (2d Cir. 2018), the court held plaintiffs had failed to plead facts suggesting that, until the actual termination of a drug candidate's development, defendants believed the drug had ceased to have promise or should be abandoned. One confidential witness conveyed to certain Individual Defendants that the preclinical trials to date had not shown the drug to be effective, but that disagreement represented a difference in opinion, especially as efficacy evidence from some of the preclinical trials suggested that defendant had at least some factual basis for their expressed optimism and "undermine[d] any circumstantial claim of recklessness." *Id.*

The cases cited by Defendants thus stand for the unexceptional proposition that a plaintiff cannot manufacture a securities fraud claim out of the good faith differences of opinion that naturally arise within a company and that experienced corporate leaders might well want to foster from their subordinates before making a decision. Those cases do not relieve a defendant from liability for failure to disclose that the FDA may demand the termination of a marketing campaign when a complaint's allegations plausibly allege both that the FDA's letter made the company aware of the risk that it would make such a demand and when a corporate insider brings that concern directly to the company's most senior leadership and the company decides to proceed nonetheless.

It is important to set forth the limits of the Court's holding. The Court does not hold that a corporate defendant, including one in the pharmaceutical industry, must disclose "every critical

comment by a regulatory agency" or that the receipt of such a comment gives rise to a strong inference of scienter. *In re Genzyme Corp.*, 2012 WL 1076124, at *10 (D. Mass. Mar. 30, 2012), *aff'd*, 754 F.3d 31 (1st Cir. 2014). There are many circumstances where the omission to disclose even a strongly worded comment will not give rise to either a misstatement or scienter—when, for example, a defendant has not made a statement giving rise to a duty to disclose or when the comment on its face or from context indicates that it is interim and subject to revision and there are no facts pled that would indicate the defendant would fail to address the regulator's comments or would be unable to do so without significant cost. *See id.* at *10-11; *see also Schaeffer*, 2020 WL 7701463, at *9.[19]

Plaintiff has alleged sufficient "additional facts" beyond the "conclusory allegation that the [FDA correspondence] alone rendered [d]efendants' public statements" regarding the promotion of the drug product misleading. *Schaeffer*, 2020 WL 7701463, at *13 (stating that there are a "wide variety of ways" to adequately allege that omission of a Form 483 is reckless, for example, "a pattern of FDA feedback reflecting the same unresolved concerns" or "other forms of regulatory feedback [that] similarly suggest that a reasonable defendant would have appreciated the gravity of the concerns raised" and citing cases). And, as the *Schaeffer* court noted, a successful showing of recklessness may "feature statements by confidential former employees reflecting that the problems identified in the [FDA correspondence] were pervasive enough that they could not be readily remedied." *Id.* at *13. In the end, Plaintiff may or may not

[19] *Perrin v. Sw. Water Co.*, 2011 WL 10756419 (C.D. Cal. 2011), upon which Defendants rely, is also inapposite. The court held that the defendant's receipt of a comment letter in which the SEC questioned the company's accounting as to two discrete items did not support an inference that the defendants had the requisite intent to defraud investors in connection with widespread accounting decisions it made over a two-year period. There is no indication from the court's decision that the items the SEC questioned had any relationship with the accounting that plaintiffs later alleged was misstated.

be able to prove the allegations, but accepting the Amended Complaint's allegations, that is what is pleaded here. *See City of Sterling Heights Gen. Emps. Ret. Sys. v. Hospira, Inc.*, 2013 WL 566805, at *18-21, 26-28 (N.D. Ill. Feb. 13, 2013) (scienter where defendants participated in various remediation meetings aimed at addressing FDA concerns, which were not routine given allegations including former employees' discussion of pervasive [] violations); *In re Able Lab'ys Sec. Litig.*, 2008 WL 1967509, at *15-16 (D.N.J. Mar. 24, 2008) (scienter where defendants "departed from the standards of ordinary care by, among other things, not adequately investigating or following up on the 2004 FDA Form 483 and warning letter," which "provided notice to the defendants that serious problems existed in the manufacturing process at [defendant], and even informed the defendants that they were responsible for following up on, and further investigating, the problems").

Plaintiff has failed, however, to plead scienter with respect to Defendants' remaining statements as there is no allegation that Defendants were aware of sales representatives' undated anecdotal reports, that Defendants were aware of the handful of negative anonymous internet reviews, or that there was any reason for Defendants to believe those experiences or reviews were representative of a meaningful number of patients. *See supra*.

D. Loss Causation

"Loss causation 'is the causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff.'" *In re Vivendi*, 838 F.3d at 260 (quoting *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005)). To plead loss causation, a plaintiff must "demonstrat[e] that 'the subject of the fraudulent statement or omission was the cause of the actual loss suffered.'" *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 179 (2d Cir. 2020) (quoting *In re Vivendi*, 838 F.3d at 261); *see also id.* ("The PSLRA 'imposes on plaintiffs the burden of proving that the defendant's misrepresentations caused the loss for which the

plaintiff seeks to recover.'") (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 345 (2005)). To do so, a plaintiff can allege either (1) "the existence of a cause-in-fact on the ground that the market reacted negatively to a corrective disclosure of the fraud" or (2) "that the loss was foreseeable and caused by the materialization of the risk concealed by the fraudulent statement." *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 233-34 (2d Cir. 2014) (quoting *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511, 513 (2d Cir. 2010)); *see also Abramson*, 965 F.3d at 179 ("Generally, plaintiffs sufficiently plead loss causation when they allege that their share's price fell significantly after the truth became known through an express, corrective disclosure or through events constructively disclosing the fraud like the materialization of [the] risk concealed.") (internal citations and quotation marks omitted).

Under the first theory, Plaintiff argues that the June 2019 Letter was a corrective disclosure that alerted the public to the falsity behind the success of the DTC campaign and "The View" segment. Plaintiff claims that the June 2019 Letter revealed Aclaris was "using advertising to promote ESKATA as part of a scheme to violate the FFDCA." AC ¶ 197. On this news, Aclaris's share price fell $0.57 per share, or over 11%, over two consecutive trading sessions to close at $4.54 per share on June 21, 2019. *Id.* ¶ 194. Defendants do not challenge the drop in stock price, but rather make only one argument in response: that loss causation cannot depend on the June 2019 Letter because Aclaris's advertising did not, in fact, violate the FFDCA, "[n]or did the letter reveal[] anything about ESKATA's efficacy and side effects, which were disclosed before the Class Period." Dkt. No. 38 at 25. But here, as the Court has concluded, the Amended Complaint alleges that the omitted information was that the FDA had taken the position that the marketing campaign upon which Aclaris rested its prospects for future success was misleading and in violation of the FFDCA. *See supra*. The June 2019 Letter

revealed that as far back as March 2018, the FDA had concluded that statements such as those in Defendants' DTC campaign and "The View" segment, were misleading and those views had not changed or been rescinded at the time of the quarterly calls when, without mentioning the FDA, Defendants touted the marketing campaign and "The View" segment as driving ESKATA's sales. Thus, the Amended Complaint can be read to plausibly allege that the June 21, 2019 stock drop was the result, at least in part, of the removal of the inflation in the stock caused by the earlier misleading disclosures regarding that marketing campaign and the promise it held for future sales of the product. *See, e.g.*, *DoubleLine*, 323 F. Supp. 3d at 458; *see also In re Barrick Gold Corp. Sec. Litig.*, 341 F. Supp. 3d 358, 380 (S.D.N.Y. 2018) (describing the burden of pleading loss causation as "a low one at the pleading stage"); *Gross v. GFI Grp., Inc.*, 162 F. Supp. 3d 263, 269 (S.D.N.Y. 2016) (burden to plead loss causation is "not a heavy one," and "when it is unclear whether the plaintiff's losses were caused by the fraud or some other intervening event, 'the chain of causation is . . . not to be decided on a Rule 12(b)(6) motion to dismiss'") (quoting *Loreley Financing (Jersey) No. 3 Ltd. v. Wells Fargo Secs., LLC*, 797 F.3d 160, 187 (2d Cir. 2015)).

Plaintiff also relies on the second theory of loss causation, the materialization of the risk. He alleges that by failing to publicly disclose that Defendants were using advertising to promote ESKATA that violated the FFDCA, Defendants concealed the risk that they would need to abruptly discontinue ESKATA. AC ¶ 197. The risk that Defendants would have to discontinue ESKATA materialized on August 8, 2019, when, in the wake of the June 2019 Letter, Defendants announced that they were discontinuing the commercialization of ESKATA, allegedly because they could not use the marketing materials previously developed including those from "The View" and because Defendants could no longer market the drug without

highlighting for customers that it was limited in effectiveness, painful and caused skin discolorations." *Id.* ¶ 198 (quoting *id.* ¶ 168). On this news, Aclaris's share price fell $0.15 per share, or over 14%, over two consecutive trading sessions to close at $0.84 per share on August 12, 2019. *Id.* ¶¶ 28, 169; *see also id.* ¶ 199.

Defendants respond that Plaintiff has not shown materialization of a "concealed risk as opposed to a disclosed risk" because the risk that ESKATA might not be commercialized successfully was extensively disclosed before the Class Period. Dkt. No. 38 at 25 (quoting *Abuhamdan*, 9 F. Supp. 3d at 209). But what Defendants miss is that the omitted fact made far more likely that ESKATA would not be marketed successfully and that Aclaris would need to cease the campaign.

The district court opinion in *In re Braskem S.A. Securities Litigation*, 246 F. Supp. 3d 731 (S.D.N.Y. 2017), upon which Plaintiff relies, is on point. There, defendant argued it did not conceal the relevant risk because it notified shareholders that a pricing agreement, which had been secretly secured by a bribery scheme, could expire or be terminated and so the market was aware defendant might not be able to indefinitely secure favorable pricing. The court rejected that argument, which it found "mischaracterize[d] the nature of the [] allegations." *Id.* at 766. It found defendant had concealed "far more" than the possibility that its favorable pricing was not guaranteed to continue when the bribery scheme ended; it "concealed a fact that made cessation of such pricing more likely—the fact that the pricing was the product of an unlawful, and hence inherently unstable, illegal bribery scheme." *Id.* When that scheme was revealed, it caused defendant's shares to drop. As such, "revelation of the undisclosed bribery scheme caused [defendant]'s stock to stop." *Id.* As in *Braskem*, Defendants here have also concealed "far more" than the possibility that ESKATA would not be commercially viable—it concealed the

truth about its misleading advertising, which the FDA found violated the FFDCA by omitting ESKATA's side effects and efficacy, that, if revealed, could make the withdrawal or failure of ESKATA more likely. And while Defendants do not raise the argument that the decline in stock price could be also attributable to other factors, Plaintiff "need not allege that their entire loss was caused by the misstatements and omissions complained of" because "misstatements or omissions that conceal a risk, the materialization of which causes all or part of the plaintiffs' loss . . . suffice." *Id.* (quoting *In re Lehman Bros. Sec. & Erisa Litig.*, 799 F. Supp. 2d 258, 305 (S.D.N.Y. 2011)).

E. Section 20(a)

Plaintiff also brings Section 20(a) claims against the Individual Defendants. To establish a prima facie case of control person liability under Section 20(a), Plaintiff must show "(1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI*, 493 F.3d at 108 (citing *S.E.C. v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1472 (2d Cir. 1996)). The first element is pled because, as discussed above, Plaintiff has alleged a Section 10(b) claim against Aclaris.

The second element, control of the primary violator, "may be established by showing that the defendant possessed the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." *First Jersey*, 101 F.3d at 1473. Control for the purposes of Section 20(a) requires that the defendant "actually possess[ed], in fact, rather than in theory, the ability to direct [the company's] actions" and that the defendant exercised "actual control over the [alleged 'misstatements']." *In re Alstom SA*, 406 F. Supp. 2d 433, 487 (S.D.N.Y. 2005). "However, '[a]llegations of control are not averments of fraud and therefore need not be pleaded with

particularity under Rule 9(b) or the PSLRA. They need satisfy only the less stringent requirements of Fed. R. Civ. P. 8.'" *City of Austin*, 957 F. Supp. 2d at 310-311 (quoting *In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430, 451 (S.D.N.Y. 2005)).

This second element is pled to each Individual Defendant. As CEO and CFO, Walker and Ruffo held the highest positions at Aclaris as officers and possessed the power to direct the management and policies of Aclaris, they participated on the quarterly earnings calls in which the actionable statements were made, and they are alleged to have been involved in discussions regarding the marketing of ESKATA. As Chief Commercial Officer, Fair also held a high-level management position and had the power to control the actionable statements; he was their maker. *See, e.g.*, *In re Emex Corp. Sec. Litig.*, 2002 WL 31093612, at *9 (S.D.N.Y. Sept. 18, 2002) (finding control where individual defendants that either held management or board positions and were responsible for drafting and disseminating the misleading press releases). As to Ali-Jackson, who was Chief Legal Officer, Chief Compliance Officer, and Corporate Secretary, AC ¶ 39, Plaintiff alleges that she, along with Walker and Ruffo, was an executive officer who "acted as the core management of the company" and was "heavily involved in every aspect of Aclaris," *id.* ¶¶ 39, 54, that she attended the PRC meetings where ESKATA's marketing was discussed, settled internal disputes regarding the marketing, personally edited the script for "The View" segment, *id.* ¶¶ 115, 125-27, and along with Walker and Ruffo, she received communications from the FDA, *id.* ¶ 124; *see also id.* ¶ 179. At this stage, these allegations are sufficient to plead control. *See, e.g.*, *In re Quintel Ent. Inc. Sec. Litig.*, 72 F. Supp. 2d 283, 298 (S.D.N.Y. 1999) (permitting Section 20(a) claim where "individual defendants influenced and controlled the decision-making of [defendant company], 'including the content and dissemination of various statements which plaintiff contends are false and misleading,'" and

plaintiffs specified that individual defendants "had access to [company]'s internal reports, press releases, public filings, and had the ability to prevent the issuance of or correct the statements"); *see also In re Nash Finch Co.*, 502 F. Supp. 2d 861, 883 (D. Minn. 2007) (permitting Section 20(a) claim against general counsel based on the "early stage of the litigation"); *Touchtone Grp., LLC v. Rink*, 913 F. Supp. 2d 1063, 1082 (D. Colo. 2012) (permitting Section 20(a) claim against chief legal officer and general counsel who was an executive officer, "was responsible for compliance with applicable statutes and regulations," "participated in the weekly staff and executive meetings," and prepared or reviewed some of the documents that contained the alleged misstatements).

As to the third element, "a split among district courts in this Circuit persists over whether culpable participation must, like scienter, be pled with particularity." *Constr. Laborers Pension Tr. for S. California v. CBS Corp.*, 433 F. Supp. 3d 515, 551 (S.D.N.Y. 2020); *see In re ForceField Energy Inc. Sec. Litig.*, 2017 WL 1319802, at *16 (S.D.N.Y. Mar. 29, 2017) ("The Second Circuit has recognized this disagreement but not yet resolved it."). Some courts in this Circuit maintain that "the Second Circuit's decision to include 'culpable participation' as an element of a prima facie case fails to convert it into a pleading requirement for a Section 20(a) claim because culpable participation is a less demanding standard than scienter." *Special Situations Fund III QP, L.P. v. Deloitte Touche Tohmatsu CPA, Ltd.*, 33 F. Supp. 3d 401, 438 (S.D.N.Y. 2014) (collecting cases). Other cases hold that "culpable participation" is an element of a Section 20(a) claim that must be pled with the same particularity as scienter. *Id.*; *see In re ShengdaTech, Inc. Sec. Litig.*, 2014 WL 3928606, at *10 (S.D.N.Y. Aug. 12, 2014) ("Most courts in this district have held that . . . culpable participation is a scienter requirement for which a plaintiff must allege some level of culpable participation at least approximating recklessness in

the section 10(b) context in order to survive a motion to dismiss.") (citations and internal quotation marks omitted).

The Court need not weigh on this split as the same facts that this Court has concluded show scienter are also particular to each Individual Defendant and therefore plead culpable participation. The third element is thus met. *See CBS Corp.*, 433 F. Supp. 3d at 551; *In re Weight Watchers Int'l Inc. Sec. Litig.*, 2020 WL 7029134, at *24-25 (S.D.N.Y. Nov. 30, 2020).[20]

F. Leave to Amend

Leave to amend should be "freely give[n] . . . when justice so requires," Fed. R. Civ. P. 15(a)(2), but "should generally be denied in instances of futility, undue delay, bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, or undue prejudice to the non-moving party," *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 28 (2d Cir. 2016) (quoting *Burch v. Pioneer Credit Recovery, Inc.*, 551 F.3d 122, 126 (2d Cir. 2008)).

"[A] district court is not required to grant leave to amend when it grants a motion to dismiss based on pleading deficiencies." *Banco Safra S.A. v. Samarco Mineracao S.A.*, 2021 WL 825743, at *5 (2d Cir. Mar. 4, 2021). Here, Plaintiff has had an opportunity to amend the complaint. "Although that amendment was not in response to a motion to dismiss identifying particular deficiencies in the pleadings, it is unlikely that the deficiencies raised with respect to the Amended Complaint were unforeseen by plaintiffs when they amended." *City of Pontiac*, 752 F.3d at 188. Importantly, in his brief requesting leave to amend, Plaintiff asserts "no additional facts or legal theories . . . [it] might assert if given leave to amend." *Id.*; *see also Born*

[20] With regard to the Section 10(b) and 20(a) claims against Fair, "[a]lthough a defendant ultimately may not be held liable as both a primary violator and a controlling person, such alternative theories of liability are permissible here." *In re Parmalat*, 375 F. Supp. 2d at 310; *see Menaldi*, 164 F. Supp. 3d at 577 n.4.

v. Quad/Graphics, Inc., 2021 WL 736839, at *16 (S.D.N.Y. Feb. 25, 2021) (denying leave to amend where "arguments made in response to the motion to dismiss give no indication that the Complaint's defects are curable"). Leave to amend is denied.

CONCLUSION

The motion to dismiss is GRANTED IN PART and DENIED IN PART. Because the Court has not relied, and need not rely, on the JAAD article, the motion to strike is DENIED AS MOOT. Dkt. No. 44.

Defendants shall file an answer to the remaining claims within twenty-one (21) days of the date of this Opinion and Order.

The Clerk of Court is respectfully directed to close Dkt. Nos. 36, 44.

SO ORDERED.

Dated: March 29, 2021
New York, New York

LEWIS J. LIMAN
United States District Judge